Moral Problems associated with Pediatric Deafness

By

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Opsomming

Doofheid in ‘n volwassene is nadelig vir kommunikasie en affekteer dus nie net die dowe person nie, maar ook almal met wie hy/sy in kontak kom. In ‘n kind jonger as 3 jaar het doofheid egter ‘n uitgesproke effek op sy/haar neurologiese ontwikkeling en mag lei tot sosiale afsondering, ‘n swak selfbeeld, leerprobleme met swak akademiese vordering en uiteindelik min werksgeleenthede. Indien die gehoorverlies nie spoedig gediagnoseer en behandel word nie, dra die kind die gevolge van die doofheid vir die res van sy/haar lewe. Erge tot uitgesproke kongenitale doofheid by kinders kan suksesvol met behulp van ‘n Kogleêre Inplanting (KI) behandel word, mits die Kogleêre Inplanting so gou as moontlik gedoen word, verkieslik op 6 maande ouderdom. Vroeë diagnose van doofheid by ‘n kind is dus uiters belangrik en hiervoor is Neonatale Gehoor Sifting (NGS) onmisbaar. NGS identifiseer dáárdie pasgebore babas wie moontlik ‘n kongenitale doofheid het en bied aan die ouers die geleentheid om die diagnose te bevestig voordat die baba 3 maande oud is.

NGS is ‘n pynlose prosedure met ‘n lae waarskynlikheid van leed. Daarteenoor, deur ‘n pasgebore baba nie vroegtydig te diagnoseer met ‘n kongenitale doofheid nie het ‘n hoë waarskynlikheid van erge leed wat aan die baba, sy/haar ouers en uitgebreide familie aangedoen kan word. Die baba en sy/haar ouers se kwaliteit van lewe sal negatief beïnvloed word indien die kongenitale doofheid eers later in die kind se lewe gediagnoseer word. Dus, het ons ‘n morele plig om universele Neonatale Gehoor Sifting toe te pas en sodoende alle pasgebore babas se gehoor te toets.

NGS help die ouers van ‘n kind met kongenitale doofheid om vroegtydig toegang te verkry tot ‘n KI (verkieslik so gou na 6 maande ouderdom as moontlik) om sodoende rehabilitasie te optimaliseer. Die Dowe gemeenskap beskou egter die beskikbaarheid van KIs as ‘n bedreiging vir hulle kultuur. Die ouers van ‘n dowe kind se besluit om ‘n KI vir hul kind te laat inplaas of alternatiewelik, om hom/haar met gebaretaal op te voed, skep morele probleme wat bespreek sal word. Die morele probleme met geselekteerde doofheid en die effek van KIs in hierdie situasie word ook aangeraak.

Doofheid in kinders word baie keer veroorsaak deur infektiewe siektes wat voorkom kan word deur inentings. Inentings is nie slegs voordelig vir die kind wat ingeënt word nie, maar skep ook kudde-immuniteit wat kinders beskerm wie om mediese redes nie ingeënt kan word nie. Daar is ‘n onlangse neiging van ouers, in veral ontwikkelde lande, om nie hul kinders in te ent

nie, met die gevolg dat siektes wat vantevore skaars was, soos byvoorbeeld masels, word nou meer algemeen. Hierdie siektes se komplikasies, onder andere, doofheid na masels en pampoentjies, word dus ook meer algemeen. Deur gebruik te maak van die Beginsel van die Minste Beperkende Alternatief en die Ingreep Leer kan aangevoer word dat verpligte inenting van kinders die getal nie-ingeënte kinders klein sal hou sodat kudde-immuniteit in stand gehou kan word. Dit is verder net regverdig dat die kinders wat ingeënt mag word, moet bydra tot die instandhouding van kudde-immuniteit. Gesondheidsowerhede is dus moreel geregverdig om inenting af te dwing deur ook die beginsel van Regverdigheid toe te pas.

Abstract

Deafness in an adult is detrimental to communication and is therefore uncomfortable and debilitating not only for the deaf person, but also for those interacting with him/her. By contrast, for a child younger than 3 years of age, deafness has a profound effect on his/her global neurological development which, later in life, may lead to social isolation, poor self-image, learning problems with reduced academic achievement and eventually limited vocational choices. If the deafness is not diagnosed and treated promptly, the child will suffer its consequences for the rest of his/her life. Congenital, severe and profoundly deaf children can be successfully rehabilitated with Cochlear Implants, only if the diagnosis of deafness is made early, preferably before 6 months of age. Early diagnosis of deafness in a child is therefore imperative. Newborn Hearing Screening (NHS) can identify those newborn babies with a possible congenital deafness and enables the parents of such a child to confirm the diagnosis with additional tests before the child is three months old.

NHS is a painless procedure with a low probability of harm. Non-diagnosis and not treating a baby with congenital deafness has a high probability of severe harm to both baby and parents, as well as the extended family. Quality of life for both the baby and the parents will be negatively affected if the congenital deafness is diagnosed and treated only later in the child's life. Therefore, we may have a moral obligation to do universal NHS, i.e. screen all newborn babies for possible hearing loss.

NHS assists the parents of a congenitally deaf child to have access to a CI for their child, when the child will benefit the most from the procedure, i.e. as soon after 6 months of age as possible. The availability and use of CIs are however viewed as a threat by the Deaf community. Deciding whether to have a CI for one's child or letting the child become part of the Deaf culture is a moral dilemma that will be discussed. The moral issues surrounding the election for deafness in one's future child and the effect CIs have on this situation, will also be discussed.

Deafness in children is mostly caused by infectious diseases which can be prevented with vaccination. Vaccination is not only beneficial to the recipient, but also creates herd immunity that protects those children who cannot be vaccinated for medical reasons. Recently, especially in developed countries, there has been a trend towards not vaccinating one's child, but the result

is that relatively uncommon diseases, like measles, as well as their complications of deafness, are re-surfacing. Applying the Principle of Least Restrictive Alternative to an Intervention Ladder, it can be argued that compulsory or mandatory vaccination is necessary to keep the number of non-vaccinated children as small as possible and thus protect herd immunity. Everyone capable of being vaccinated, should do so, to compensate for those who cannot be vaccinated for medical reasons and can therefore not contribute to herd immunity. Compulsory vaccination may therefore also be morally justified by applying the Principle of Fairness.

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Chapter 1: Introduction

Deafness in the pediatric population must be avoided and if present, should be treated effectively as soon as possible. The ethical issues surrounding vaccination (avoiding deafness in children), diagnosing deafness as soon as possible (NHS) to facilitate effective treatment (CI or sign language), need to be addressed. Is enforced vaccination against childhood diseases morally justifiable? May all newborns be subjected to NHS? What information should be given to parents of a newly diagnosed deaf baby/child with respect to treatment? This thesis attempts to solve these moral problems by objectively analysing all possible options. The conclusions of this thesis may feasibly be used to introduce policies relating to the subject.

Conceptual research was used by evaluating theories and empirical data acquired from books and articles available in libraries and on the internet. The thesis does have its limitations. Avoiding bias is not always possible, but the author attempted to minimize it by discussing all possible options. Some opinions may not have been discussed because of not accessing all information on the subject. Also, there are other conditions causing pediatric deafness which may create ethical/moral problems, but have not been discussed, for example: if, when, and how to treat otitis media (middle ear infection). Arguments used in this thesis may be of value in discussions on other conditions relating to pediatric deafness.

It is crucial for a discussion concerning the moral problems associated with pediatric deafness to first of all define deafness, then to determine whether it may be classified as a disability and whether treating deafness should be viewed as an enhancement. Thereafter, I discuss a clinical case which illustrates some ethical conundrums and then investigate features that influence pediatric deafness.

1.1 Deafness

Hearing is a particularly important sense as it is a way of communication, it makes us aware of our environment, warns us of possible dangers, and gives us the pleasure of appreciating music.

Deafness is classified by referring to the Type of deafness as well as the age of Onset of deafness and Severity. If the deafness is caused by an obstruction in the ear canal or ossified ossicles, it is called a Conductive hearing loss. Damage to the cochlea, e.g. congenital conditions or an infection, like meningitis, causes a Sensorineural hearing loss. A hearing loss due to damage to the acoustic nerve or brain, is called a Central hearing loss. When the hearing loss takes place in relation to the acquisition of speech, makes it Prelingual, Perilingual or Postlingual (see below). The degree of hearing loss is measured in decibels (dB) and classified in terms of pure tone average (PTA), the average of hearing thresholds for pure tone sounds, measured at 500, 1000 and 2000 Hz. Sensorineural hearing loss is further classified as Mild (PTA:25-40dB), Moderate (PTA:40-70dB), Severe (PTA:70-95dB) and Profound (PTA more than 95dB).

Deafness has a profound effect on the development of speech; therefore, it is described as Prelingual if it is present before the development of speech (i.e. before the age of 2 years), Perilingual if it occurs after some spoken language has been acquired, but before language development is complete (i.e. between 2 and 5 years), and Postlingual if it happens after the acquisition of speech (i.e. after the age of 5 years).

A prelingually deaf child is either born with the hearing loss or has acquired it before the age of 2 years. Congenital deafness is present at birth and can be caused by genetic or nongenetic factors. Genetic mutations are responsible for approximately 50% of congenital deafness cases, 25% are attributed to environmental factors and in 25% of cases the etiology is unknown. The genetically caused deafness cases are further divided into syndromic, where the deafness is part of a syndrome, e.g. Pendred (hypothyroidism and bilateral sensorineural deafness) or Usher syndrome (sensorineural deafness and loss of vision due to retinitis pigmentosa), or nonsyndromic deafness. Environmental factors include maternal infections such as Rubella or Cytomegalovirus, drugs or toxins consumed by the mother during pregnancy, prematurity, birth injuries or jaundice caused by Rh factor incompatibility.

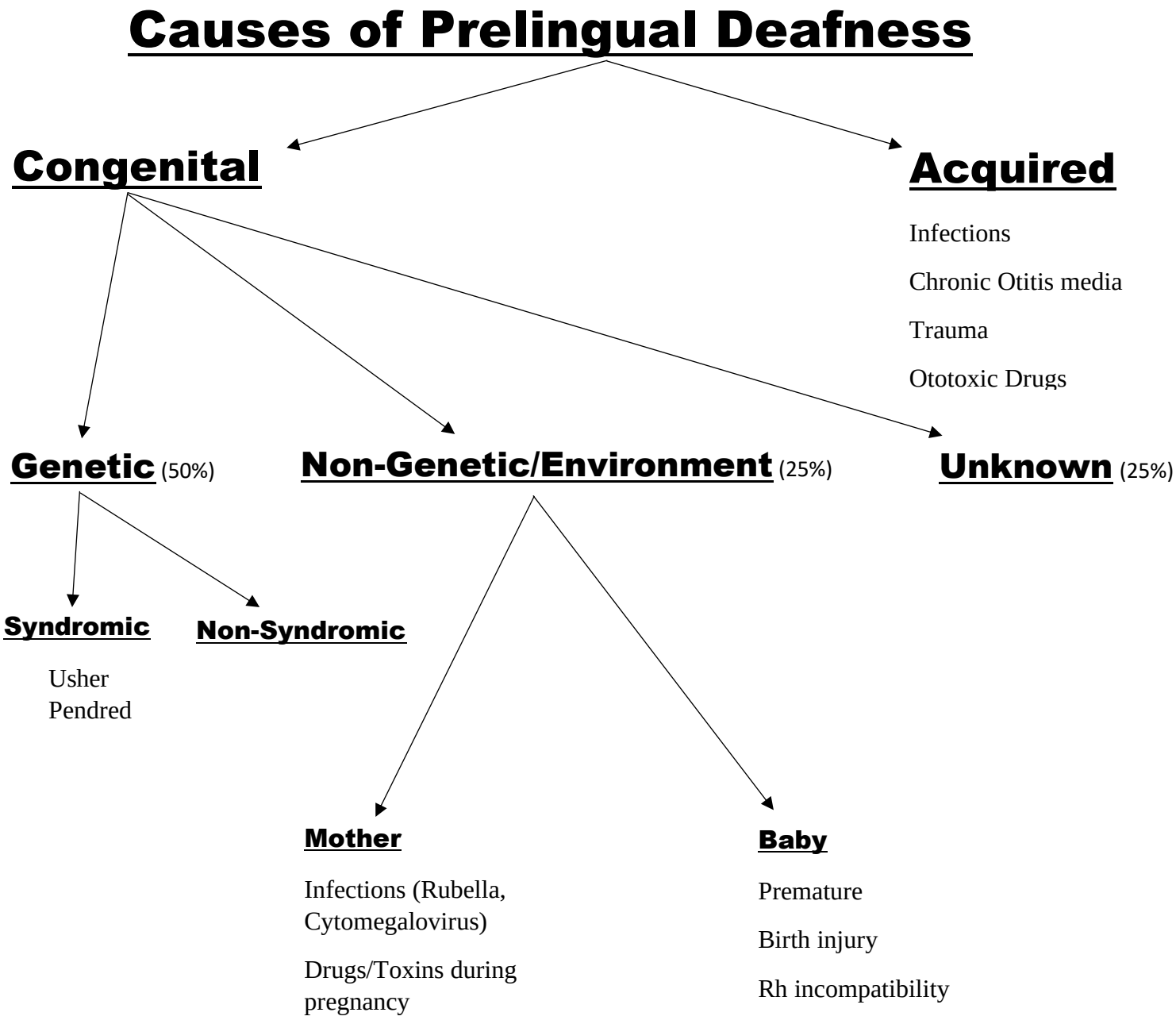

Figure 1

Objectively diagnosing a hearing loss in a prelingually deaf child is possible by using Otoacoustic Emissions (OAE) and Auditory Brainstem Response (ABR). With an incidence of 1-3 per 1 000 live births, Sensorineural hearing loss is the most common congenital sensory deficiency.

Postlingual deafness in children is caused by meningitis, mumps, measles, chronic otitis media, trauma or ototoxic drugs. Meningitis is the most common cause of postlingual hearing loss in children. A child with bacterial meningitis has a 10% chance of developing significant sensorineural deafness. Bacterial meningitis is usually caused by Haemophilus influenzae, Streptococcus pneumoniae or Neisseria meningitidis. Children can be immunized against Haemophilus influenzae infections with the Hib vaccine and against Streptococcus pneumoniae infection with Prevenar 13 which protects against the 13 most common strains of pneumococcus. Measles and mumps are highly infectious viral diseases which can be prevented by immunization with the triple MMR (measles, mumps and rubella) vaccine.

Deafness can be treated by removing the obstruction causing a Conductive deafness (for example, impacted ear wax), or amplifying sound with a hearing aid to treat a sensorineural hearing loss. Amplification with a hearing aid is only effective in mild and moderate sensorineural hearing loss. Severe and profound hearing loss can be treated with a Cochlear Implant.

Parents of severe and profoundly deaf children, (pre-, peri-, or-postlingual) face a dilemma, because they must decide on a treatment for their child. In a prelingually deaf child, the parents' dilemma is compounded because they do not have many months to decide whether to have their child implanted, as hearing is important for the child's speech development. If a child develops a sensorineural hearing loss after meningitis, the cochlea becomes ossified within a few months, which makes a CI very difficult or even impossible. Parents of these children also do not have long to decide on a CI or not.

The parents' decision will also impact hugely on the child's future life: if they decide not to let their child be implanted, they must expose their child to another form of communication (Sign language) which is very different to their own. Deaf, with an upper case "D", implies the Deaf culture whose members use sign language to communicate and have the same customs and values. Being deaf is a valuable characteristic in the Deaf culture and Deaf parents would prefer deaf children to incorporate them into their own culture. Although the Deaf community is a

minority culture, it has intrinsic and special value according to Levy (2002a:151). He also states that the parents of a deaf child are under no obligation to support the Deaf culture by deciding against a CI for their child. If they do decide to let their child be implanted, it exposes their child to an operation early on in life and the child must have access to an audiologist and speech therapist for the rest of his/her life. Their decision will thus have profound psychological and societal consequences for their child. It is therefore imperative that they make an informed decision.

The diagnosis of deafness in a child of hearing parents is often viewed as a crisis by the parents. When a child is born, her/his parents hope that the child will have access to all of life's options and they perceive that deafness will exclude their child from this. Hearing loss is not visible at birth, therefore the parents usually (unless the child was screened directly after birth) only find out about the handicap/disability when the child is between 18 months and 3 years old (Niparko 2009:147-148). Parents of a newly diagnosed child with a hearing loss typically go through the following stages: shock, recognition, denial, acknowledgement and eventually, constructive action. Parental stress in mothers of three groups of preschool children (healthy, hearing impaired and seizure disorders) were compared and mothers of hearing-impaired children reported the highest levels of stress and the greatest number of depressive symptoms. Parent's values and priorities play an important role in their reaction when they find out that their child is deaf: parents who value literacy and education will have more concern for their deaf child than those who have lower expectations. Rehabilitating a deaf child requires ongoing commitment from the whole family and poses a constant challenge regarding communication, discipline and time management.

The lack of auditory stimulation from the environment during early childhood disrupts the normal development of the auditory system and hampers the acquisition of language skills according to the concept of neuroplasticity.

1.1.1 Neuroplasticity

Neuroplasticity describes the brain's ability to learn new skills, integrate and retrieve memories, reorganize neuronal networks in response to environmental stimuli and recover after lesions (Casshilas et al, 2015:976). This neuronal plasticity is achieved by implementing neurogenesis (production of neurons by neural stem cells), cellular apoptosis (programmed, regulated cell death), synaptic-dependent activity and reorganization of neuronal networks. During the first 3 years of life (so-called 'sensitive or critical period'), the child's brain has a bigger capacity for plastic reorganization and can develop new neural pathways in response to auditory stimuli or the lack thereof. In a normal hearing baby, synaptogenesis (formation of synapses in the nervous system) in the temporal cortex peaks at approximately 2 to 4 years of age (Kral and Sharma, 2012:117), which correlates with the ideal age for the best results with a cochlear implantation. When sound is not present, the brain re-organizes itself to use input from other sensory organs, especially sight: this is called cross-modal reorganization. Waltzman and Roland (2014:38) define this neuroplasticity as *"*the capacity of the brain to be modified by changes in patterns of sensory experience and motivational state*"*. Therefore, external stimulation during early development is especially important to produce functional networks and neural connections. Auditory deprivation results in abnormal or delayed maturation in the auditory cortex (Waltzman and Roland, 2014:42). These factors are the rationale behind early cochlear implantation in children which, after a short period of deafness, gives the best language acquisition results (Vincenti et al, 2014:6). According to the Tygerberg Hospital Cochlear Implant Unit, the optimal time to implant a prelingually deaf child is before 3 years of age, but ideally before 12 months of age (Lombaard, 2019). Bhamjee et al (2019:7) found that the majority of parents of CI children in South Africa felt that the time between the diagnosis of a hearing loss and eventual cochlear implantation was too long and that this could be attributed to financial factors. This was confirmed by a study in India (Dev et al, 2018:338-349). Neuroplasticity is responsible for the phenomenon where word recognition, in adult patients after a CI, improves by about 50% during the first postoperative year (Waltzman and Roland, 2014:38).

To a lesser extent neuroplasticity also occurs in the mature brain and is influenced by the quality and quantity of the sensory experience according to Voss et al (2017:4). They admit that neuroplasticity within sensory systems is greatest during early development ('critical/sensitive period') but conclude that neuroplasticity in the adult brain can also be achieved and even

modulated by manipulating neuromodulators and sensory input (Voss et al, 2017:8). Casshilas et al (2015:979) cite animal and human studies that have reported positive effects of physical exercise on spatial learning and memory because of neuroplasticity in the hippocampus. The onset of dementia can be delayed by enhancing neuroplasticity, according to Shaffer (2016:2). She discusses five factors that may improve neuroplasticity and cognitive function (Shaffer, 2016:2-6): novelty and challenge, diet and inflammation, sleep, exercise, and love, perception and reduced stress.

The relationship between age-related hearing loss (ARHL) and dementia has been studied by various authors. Su et al (2017:2330) found that among patients with ARHL there was a higher incidence of subsequent dementia. They showed that age was the most important risk factor for developing dementia, followed by comorbidities (chronic liver disease, rheumatoid arthritis, hypertension, diabetes mellitus, stroke, head injury, chronic kidney disease, coronary artery disease, alcohol and tobacco abuse), then hearing loss and female gender. They suggest that ARHL can be used as a marker for dementia (Su et al, 2017:2331). Auditory stimulation may increase neuroplasticity and prevent, or at least delay, dementia.

The medical community sees deafness as a disease or disability which can be treated or enhanced, but the Deaf society views deafness as an existential characteristic which should not be removed/treated/enhanced. These two fundamentally different views of deafness surround the debate on cochlear implantation in pre-and-perilingually deaf children.

1.2 Disability

To understand disability, it is important to understand what is meant by the term “normal function”. The word normal has its origin in the Latin word norm/normalis which means a carpenter’s square. Synonyms are: usual, standard, typical, common and ordinary. In the English language the word normal appeared in approximately 1850 (Davis, 2013:2). Glover (2006:12) views “normality that is contrasted with disability is a hybrid of the numerical and the normative”. Normality can thus be determined numerically – a function, or potential function, demonstrated by a sizable past or present population (Van Niekerk, 2013:106).

The WHO view the term disability to include impairment, limitation to activities and participation restriction. It is not only a health problem, but a complex association between a person's body and the characteristics of the society in which he/she lives.

A disability can be defined medically, socially, and philosophically according to Van Niekerk (Van Niekerk, 2013:105). A ***medical*** disability is the result of disfunction of a part or parts of the human body or mind and can be caused by genetic factors, disease, or accident. This disfunction results in impaired abilities to cope with life. A ***social*** disability is an adverse condition relative to how society functions, but even when society is radically changed, many disabilities remain. He uses the situation of an 18th century community, known as Martha's Vineyard, to demonstrate how a society can accommodate and accept a disability so that it becomes hardly noticeable and is widely accommodated. The ***philosophical*** view of a disability takes the limitations in bodily and/or mental function into consideration. He finally defines a disability as *"*a physical or mental condition, characterized by significant functional impairment, that most people have a strong rational preference not to be in*"*. Therefore, deafness is a disability according to all these definitions of the term.

Deafness is a disability according to Levy (2002a:149) because the disadvantages suffered by deaf people are mainly natural and, to a lesser extent, social in origin. Society has already corrected some of the disadvantages suffered by the deaf by, for example, providing sign-language interpreters and captioned television programs, but it remains a major disadvantage not to hear sounds that alert us to possible dangers, like car horns and fire alarms. Also, the average deaf person reads at a fourth-grade level; one in three drops out of high school; only one in five who enters college gets a degree. They earn 30% less than the general population; their unemployment rate is high, and when seeking employment, they get manual jobs such as kitchen workers, janitors, machine operators, tailors, and carpenters, which do not require good language abilities. He sees hearing as a sense that cannot be shut off easily (comparing it to sight) or focused in one specific direction; hearing is therefore multidirectional (Levy, 2002a:140). We hear whether we listen or not.

Treating the disability of deafness with a hearing aid or a Cochlear Implant to improve the patient's hearing to a nearly normal level, therefore enhances his/her well-being. Limiting the number of deaf children in a community, by using Newborn Hearing Screening to diagnose and treat deafness promptly, may be viewed as an enhancement of society. To prevent infectious disease that may cause deafness by improving the immune respons of individuals

with vaccinations, is also an enhancement. This enhancement benefits not only the individual, but also the community, locally and globally.

1.3 Enhancement

Enhancement is the process of improving the quality, amount, or strength of something. Human beings have always tried to improve themselves or the environment by using enhancement techniques. Literacy is one example of human enhancement and has enabled us to write our thoughts down, argue about them and so enhance our cognitive functions. Institutions, i.e. the phenomenon of people acting together, and not only as individuals, are another example of an enhancement: they enhance our ability to use resources and ensure that we live in peace and security. The development of agriculture, by creating food security, is another example of enhancement.

Buchanan (2011:23) defines biomedical enhancement as: "a deliberate intervention, applying biomedical science, which aims to improve an existing capacity that most or all normal human beings typically have, or to create a new capacity, by acting directly on the body or brain". He names five types of enhancement that are commonly discussed in the literature: improvement in physical characteristics (speed, strength, endurance), improvement in cognitive functions (memory, information-processing, reasoning), improvement in affect (emotion, motivation, temperament), improvement in immunity (resistance to infections, i.e. vaccinations) and longevity. Whereas Buchanan sees enhancement as applicable only to interventions that improve normal functions, Van Niekerk (2013:108) applies the term enhancement to other interventions that restore normal function in persons who are disabled. Therefore, a Cochlear Implant enhances hearing of deaf (disabled) people to a nearly normal level.

Prenatal Genetic Diagnosis was developed to improve the success rate of In Vitro Fertilization by identifying genetically normal embryos to implant in the mother's uterus. By not allowing genetically abnormal embryos to develop, this procedure enhances the whole community.

CRISPR/Cas9 technology, developed during the past decade (Mali et al, 2013:826), has made human genome editing not only possible, but more precise, simple, and cheap, according to Dhai (2019:49). This technology has the potential to eradicate genetic diseases and is surely also an enhancement of humanity. The application of this technology, and the ethics thereof, is

still being debated. Lewens (2020:7) is concerned that the ethics of 'non-genetic inheritance' is not receiving enough attention.

The following case study highlights some of the ethical issues parents face when having to decide whether their child should receive a CI.

1.4 Case Study 1

Adam (McCormick, 2010:1186) was diagnosed with congenital deafness with neonatal screening tests and a full diagnostic workup showed that he would benefit by a CI. His parents were both hearing but his uncle was deaf, used sign language to communicate, and was a highly active member of the Deaf community. While Adam's parents were exploring the option of a CI for him, his uncle confronted them with the alternative, i.e. to allow him to learn sign language, be incorporated in the Deaf community and when he turned 18, he could decide for himself whether he would like a CI. The uncle was also concerned about the possibility of Adam getting meningitis because of the CI. Adam's parents were in a state of conflict about the uncle's suggestion that Adam should be assimilated into the Deaf culture, or whether he should instead, be given a CI and so become part of the hearing culture, with all its benefits and opportunities.

Humphries (Humphries et al, 2012: 202) suggests that the ideal situation would be to let a child have a CI, but learn sign language as well. Adam's parents will have to learn sign language as well, to help him develop his communication skills. McCormick (2010:1188) uses Jonsen et al's "4-box method" to help identify the ethical question, come to a reasonable conclusion, and recommend a plan of action. The 4 boxes are: Medical Indications, Preferences of Patients, Quality of Life, and Contextual Features (Jonsen et al, 2015:9). The purpose of these four boxes represents a method to collect and arrange information relevant to a specific case. Answering all the questions in each box will give a comprehensive account of the ethical issues of a particular case.

Medical Indications/Facts – apply the principles of Beneficence and Nonmaleficence to the diagnostic and therapeutic interventions necessary to diagnose and treat the specific medical condition;

Patient Preference – determine the choice(-s) of the patient or his/her surrogate regarding his/her treatment by using the principle of respect for Autonomy;

Quality of Life – construe the degree of well-being or distress and impairment before and after treatment using the principles of Beneficence, Nonmaleficence and Respect for Autonomy;

Contextual Features – recognize the social, institutional, financial, and legal factors applicable to the medical decisions in a particular case by using the principles of Justice and Fairness.

Applying the four box method to this case, McCormick (2010:1188) concludes: the patient has a congenital deafness and is a good candidate for a CI; follow-up speech therapy and audiology are available close to his home; the patient is a minor but his parents are the appropriate surrogates with his best interest at heart, and are well informed about the risks of surgery and the necessary follow-up services; quality of life is affected by the ability to hear and to develop speech which can be achieved with a CI; insurance will cover the cost of the CI and rehabilitation.

The cultural element (contextual feature) in this case is the uncle who is an active member of the Deaf culture and would like his nephew to become a member of this culture by not having a CI, and he was also concerned about the possibility of meningitis after a CI. The parents and the uncle should be counselled with respect to the very low incidence of meningitis after a CI and they must be made aware of the fact that having a CI after 18 years of deafness has a very poor prognosis for speech development. The parents are competent to decide for their child because they have the capacity to communicate, understand, reason, deliberate and they should know what is best for their child. The parents were exposed to conflicting options for their child, but after having both options fully explained to them (informed consent), they must be assured that the final decision is theirs, because they are the surrogate decision makers for their child and not the uncle. They should act in the best interest of their child. The CI-unit is compelled to emphasize the problems of raising a child with sign language in a household with hearing parents, and they should therefore recommend a CI. To avoid discord in the family, the CI-team should involve a social worker or chaplain who can help to maintain the family unity as far as possible.

1.5 Influences on Pediatric Deafness

Maternal rubella is one of the causes of congenital deafness in babies, while meningitis, caused by Haemophilus influenzae and Streptococcus pneumoniae, and mumps are the most common causes of postlingual deafness (deafness occurs after the acquisition of speech) in children. All these infections can be prevented with vaccinations in accordance with the old saying, "prevention is better than cure". In contrast, not having vaccinations against these infections will result in higher incidence of pediatric deafness and the need for more Cochlear Implants, hearing aids and hearing rehabilitation. This will put available resources under pressure. Recently, there is a trend towards not vaccinating one's children against these infections; therefore, a discussion about the ethics of vaccination is vital when discussing moral issues in Pediatric deafness.

It is in the best interests of the deaf child that the hearing loss is diagnosed as soon as possible to facilitate prompt treatment, for the best possible prognosis for speech development. Newborn Hearing Screening (NHS) provide early diagnosis of congenital deafness so that the appropriate children may be helped with hearing aids or Cochlear Implants. Although NHS is endorsed by the WHO and the HPCSA, it is not routinely performed on all newborn babies in South Africa. There are various reasons for this, but the moral issues of not doing NHS will be discussed.

Cochlear Implants have revolutionized our treatment of deafness and especially pediatric deafness. Deaf children, having had a CI, have nearly normal speech development, and have all the usual opportunities of a hearing child. It is, however, not an insignificant intervention and the life-long follow-up for rehabilitation may be daunting. The effect it might have on the Deaf community, is a topic of intense debate. Moral issues about whether one should subject one's child to a CI will be discussed, as well as those relating to elective deafness.

Chapter 2: Cochlear Implant

2.1 History of Cochlear Implants

The cochlear implant (CI) has revolutionized our treatment of severe or total deafness over the past 50 years. It is therefore regarded as one of the great advances in modern medicine. It offers the parents of a deaf child the choice of near normal hearing by means of a CI or raising their child with sign language. Both options will give the child the opportunity to communicate and thus facilitate cognitive development and be incorporated in a society.

On 25 February 1957, Charles Eyriès (1908-1996), Chief of Otorhinolaryngology and Head and Neck Surgery at L´Institut Prophylactique in Paris, with the help of an electrophysiologist in the Department of Anatomy and Physiology at the Faculté de Medicine in Paris, André Djourno (1904-1996), implanted the first electrode in a patient's cochlea, i.e. hearing part of the inner ear (Niparko:2009:89). The patient could hear environmental noise and some words but could not understand speech. This work was published only in French, but a patient of William House drew his attention to it.

In 1960, William F. House (1923-2012), in practice with his half-brother Howard House at the Otologic Medical Group in Los Angeles, received the article by Djourno and Eyriès. He was inspired by their work and together with a neurosurgeon, Dr. John Doyle, implanted two volunteers with a simple gold wire electrode that was brought out through the skin. The same hearing results were obtained as those by their colleagues in Paris, but the electrodes had to be removed because of infection (House, 2013:67). Even implanting the device under the skin caused infection and rejection of the implant. Concerns for infections and rejection of the implant led to House postponing work on the implant for several years.

Doyle, however, continued to implant more patients and in 1967 House became interested in CIs again when he saw the success of other implantable devices such as pacemakers and ventriculoperitoneal shunts. Unfortunately, sensationalized and premature claims of an artificial ear in the lay press lead to pessimism among scientists and engineers. Undeterred, House partnered with Mr. Jack Urban, an electrical engineer, and produced an implant that was used in many patients. House is seen as the "father" or pioneer of the CI. Robin Michelson, an

otologist, and Michael Merzenich, a neurophysiologist, at the University of California-San Francisco, also implanted a few patients.

All the cochlear implants however, only stimulated one area in the cochlea, the so-called single-channel electrodes. In 1976 the National Institutes of Health tasked Dr. Robert C. Bilger (Eshraghi et al, 2012:5) to evaluate thirteen patients who had received cochlear implants. He concluded that the single-channel devices did not make speech understanding possible, but did enhance speech production, lip reading and quality of life (the so-called "Bilger report").

The application of technological advances in the aerospace and computer industries resulted in miniaturization of the receiver/stimulator device and improved safety and durability. In 1980 the House 3M device was approved by the FDA and the criterion for use was lowered from 18-year-old patients to 2 years old.

In 1981 House implanted a 3-year-old girl who had lost her hearing because of meningitis. He was severely criticized for this: Dr. Robert Rubin, a well-known pediatric otolaryngologist said: "There is no moral justification for invasive electrodes for children". He described a Cochlear Implant as a costly and cruel incentive that was developed to console concerned parents of deaf children, who would do anything to enable their children to hear (House, 2011:89). Two other groups however, at the University of California-San Francisco and Graham Clark at the University of Melbourne in Australia, together with House, developed the multi-channel electrode which was introduced in 1984. This multi-channel device resulted in improved speech recognition and was approved by the FDA for adults in 1985, and for children from 2 years old in 1990. Mainly multi-channel devices are available at present and by applying new technology, these devices improve speech recognition.

Congenitally deaf children can be diagnosed soon after birth with neonatal hearing screening, but it is important to follow up on these children so that they can be rehabilitated by means of a cochlear implant. House developed a screening test that can even be done by the mother, which he called the *Sleeping Baby Home Hearing Screen* (House, 2011:100). Implanting children at an early age results in improved language development. Implanting deaf children at the age of 6 months is now commonly done.

Initially, in the early 1970s, many otologists and auditory scientists were very skeptical of the cochlear implant because they argued that it was a very crude and distorted stimulation of the hearing nerve. Critics wanted animal studies to determine its effectiveness, but these studies were difficult or impossible to perform because speech perception could not be tested in

animals. Technological improvements in the devices resulted in dramatically improved speech perception. The effectiveness of the cochlear implant is no longer in dispute, but when it should be implanted, is controversial.

The oldest CI unit in South Africa is situated at Tygerberg Hospital (Tygerberg Hospital-Stellenbosch University Cochlear Implant Unit) where the first cochlear implant was performed in 1986 by Dr. Derrick Wagenfeld. To date, over 800 patients have been implanted at Tygerberg Hospital Cochlear Implant Unit. Presently there are 10 CI units in South Africa.

2.2 Anatomy of the Ear

The ear consists of three parts: the external, middle and inner ear.

External Ear

The outer ear has two parts, the auricle or pinna (that which is visible) and the ear canal. Cartilage of the pinna is continuous with that of the lateral third of the ear canal (Gleeson, 2008:3106). The medial two thirds of the ear canal are formed by bone. The ear canal is approximately 2,4 cm long and is slanted downwards and forwards towards the tympanic membrane/eardrum. The ear canal is lined with specialized skin and contains hair (laterally) and wax glands (medially).

Middle ear

The middle ear contains the ossicles (small middle ear bones): malleus laterally (largest of the three ossicles, measures approximately 9 mm in length), incus in the middle and stapes medially. The stapes footplate is 3 mm long and 1,4 mm wide (Gleeson, 2008:3115) and fits into the oval window. Gleeson (2008:3115) describes two muscles (tensor tympani muscle connected to the malleus and stapedius muscle connected to the stapes) which are responsible for dampening of loud sounds. Anteriorly, the middle ear communicates with the nasopharynx (back of the nose) via the Eustachian tube and posteriorly with the mastoid air cells. The ossicles are responsible for transferring sound waves from the eardrum to the inner ear.

Inner ear

The inner ear consists of the cochlea (for hearing) anteriorly and the semicircular canals (for balance) posteriorly. The cochlea forms the medial wall of the middle ear and communicates with the middle ear via two windows: the oval window superiorly and the round window inferiorly. The oval window is covered by the footplate of the stapes and the round window by a membrane. The cochlea is shaped like the shell of a snail and makes 2¾ turns around its axis, called the modiolus.

Transecting the cochlea reveals three chambers: superiorly is the Scala vestibuli, in the middle, the Scala media and inferiorly, the Scala tympani. The Scala media contains endolymph, whereas the Scala tympani and Scala vestibuli, contain perilymph. The organ of Corti, which contains the hair cells, is in the Scala media. The hair cells are arranged in two rows – a single row of inner hair cells and outer hair cells consisting of three rows (Gleeson, 2008: 3130). Nerves from the hair cells form the spiral ganglion which is closer to the Scala tympani than to the Scala vestibuli. Nerve fibres from the spiral ganglion form the acoustic nerve which runs via the internal acoustic canal to the auditory cortex in the temporal lobe of the brain.

When the hair cells have been damaged, or are absent, causing deafness, the electrode array of a CI can be placed in the Scala tympani to stimulate the nerves of the spiral ganglion.

2.3 Physiology of Hearing

The ear is for hearing and balance. The function of the outer ear is to direct soundwaves onto the eardrum. The eardrum and middle ear ossicles amplify soundwaves and transform soundwaves in an air medium to soundwaves in a water/liquid medium (perilymph in the Scala tympani and Scala vestibuli) in the cochlea.

The wave in the cochlear fluid (called a traveling wave) cause movement of the hair cells in the Organ of Corti in the Scala media. This hair cell movement triggers the release of neurotransmitters which stimulate the acoustic nerve fibers, i.e. it produces an electrical current in the acoustic nerve (Gleeson, 2008:3131). The organ of Corti thus converts physical vibrations into an electrical respons. High frequency sound is detected by hair cells in the organ of Corti in the basal/first part of the cochlea and lower frequencies by hair cells in the apex of the cochlea (Gleeson, 2008:3131). This current is carried in the acoustic nerve to the

auditory cortex in the temporal lobe of the brain. Movement of the hair cells emit sound, i.e. cochlear echoes (also called oto-acoustic emissions) which can be measured in the ear canal with extremely sensitive equipment (Gleeson, 2008: 3200).

2.4 Device

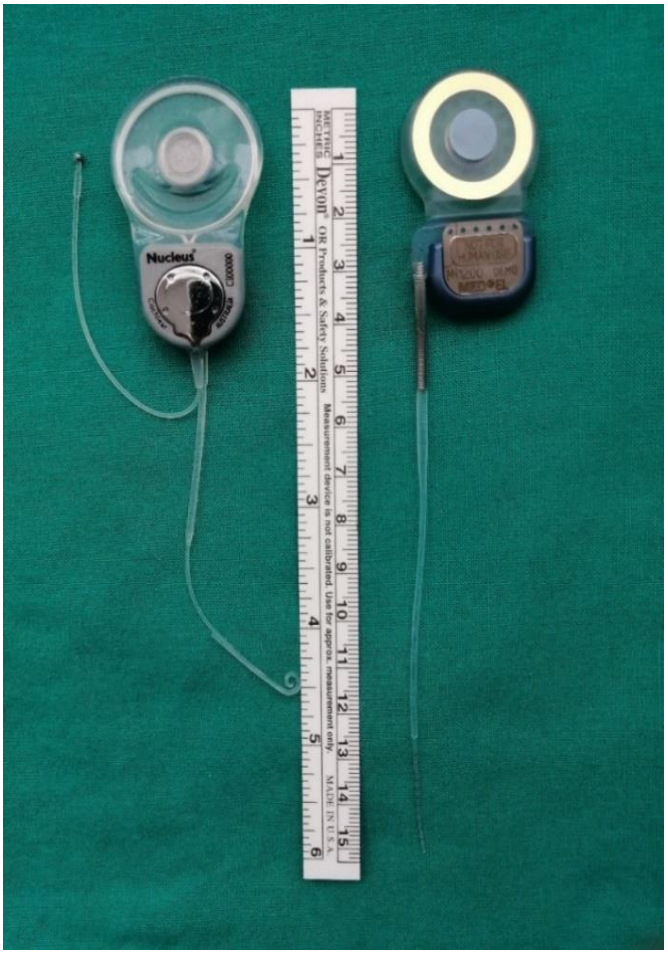

Figure 2: Internal or implantable devices from Nucleus® (left) and Med®El.

A cochlear implant consists of two parts: the part that is implanted and the part that fits on the skin covering the implant. The implant proper consists of a receiver which is seated in a socket created in the skull behind the ear and an electrode array which is placed in the Scala tympani of the cochlea. The receiver is also a magnet on which the transmitter of the outer part clips. The transmitter is connected to the speech processor which has a microphone.

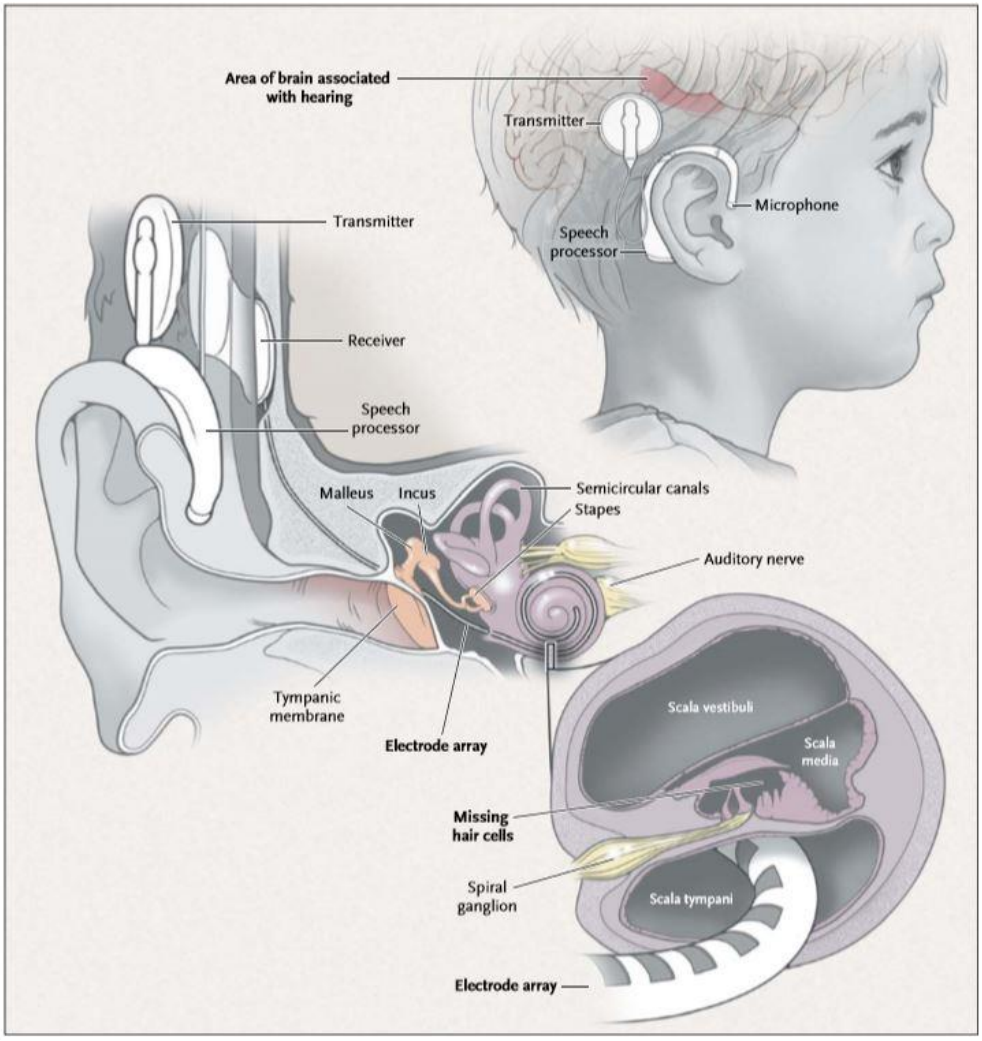

Figure 3: Function of a Cochlear Implant within the Ear (O'Donoghue, 2013:1192)

Device safety is very important and has been studied extensively (Gleeson, 2008:3652). The following factors were considered to make the device as safe as possible:

- biocompatibility of the materials used in the construction of the receiver and the electrode array,
- to minimize the trauma to the Scala tympani when the electrode is inserted,
- to prevent infection of the cochlea after insertion of the electrode,

- the effect of acute and chronic electrical stimulation on the cochlea and auditory nerve.

The electrode array must comply with the following (Waltzman and Roland, 2014:108-115):

- it must be long enough and have multi-channels to stimulate multiple areas in the cochlea,
- it must be as thin and soft as possible to minimize trauma to the residual hair cells in the cochlea,
- it should curve in the Scala tympani to hug the modiolus and thus be as close as possible to the spiral ganglion,
- it must be inert and not allow infection to spread to the middle ear or cochlea.

A cochlear implant is an expensive prosthesis plus the many hours of rehabilitation necessary after an implantation, justifies careful consideration before embarking on this route.

2.5 Cost-Utility of CI

Cost-utility analysis (CUA) is used to determine cost in terms of quantity and quality of life. It compares two different interventions with different benefits and is similar to cost-effectiveness analysis. Cost is measured in monetary terms and utility in Quality-adjusted Life Years, or QALYs. Quality of life is expressed (Beauchamp and Childress, 2013:239) as a utility value between 0 (dead) and 1 (perfect quality of life). CUA makes it possible to measure different health interventions in money/QALYs gained.

Semenov et al (2013: 403) used the Childhood Development after Cochlear Implantation (CDaCI) study to determine the effect age at CI has on cost-utility. They studied three groups: children receiving a CI at younger than 18 months of age, between 18 months and 36 months and older than 36 months. They found that CI was cost effective in all three age groups but implantation in children younger than 18 months of age had the best results (2013:407). They also state that one of the barriers to early implantation was the poor follow-up after Newborn Hearing Screening (2013:408).

Although the CI device is expensive (approximately R300 000), Emmett et al (2015:1363) showed that a CI is more cost-effective than deaf education in sub-Saharan Africa. Developing

countries face unique challenges of which the cost of the CI device and access to rehabilitation are the most important. Bento et al (2018:207) compared the cost-effectiveness of deaf education with CIs in South America and found them to be equally cost-effective, but they did not compare the long-term differences in economic productivity between the two groups.

To overcome the problem of access to rehabilitation in India, Kumar et al (2018:199) devised the so-called ‘hub and spoke‘ model where satellite rehabilitation units were established in the rural areas closer to the patients’ homes. Remote programming of a cochlear implant using telecommunication may improve access and reduce cost, according to Magro et al (2018:193).

Lack of neonatal hearing screening because of poor infrastructure leads to the delay in diagnosis of congenital deafness and consequential increased cost for older children. CI candidate selection plays an important role in the cost-effectiveness of a CI – better candidates will perform better and require less rehabilitation. Stricter criteria in developing countries ensure maximum success and minimal nonuse of the CI. Funding of the CI also affects the criteria: Raine and Vickers (2017:2) showed that criteria are less strict in countries where public funding is not provided.

A cochlear implant is an example of a modern technology that can alleviate the suffering caused by deafness (disability). Hintermair and Albertini (2005:188) state that time plays an important role in CI, as it does in all new communication technologies: the diagnosis of deafness must be made as soon as possible (neonatal hearing screening), the CI must be implanted as soon as possible to stimulate the child’s brain during the sensitive period, and a hearing aid can be tried out, but for a short period only (in an adult). New technologies (CI) may create new problems; for instance, new dependencies may develop: a young man may decide to remove his cochlear implant because he does not want to be dependent on the technology and medical care providers. They suggest that when dealing with parents of deaf children, we must always consider the psychological state of those affected (Hintermair and Albertini, 2005:190) and “fascination with new technologies should not replace sound educational or psychological principles, ethical practice, or socially agreeable and peaceful human interaction.”

2.6 Indications

A possible candidate for a CI must be comprehensively assessed by a multidisciplinary team because it involves not only surgery, but also long-term intervention managed by various professionals. Niparko (2009:137) states that the following should be kept in mind when evaluating a candidate for a CI:

- a CI is a communication tool and does not cure cochlear hair cell loss,
- communication disorders are multifaceted and thus need more than one rehabilitative strategy,
- candidates or their parents must be motivated and have a good support system and psychological composition to optimally use the device,
- preoperative guidance will help the candidate or parents to temper their expectations with the likely outcomes.

Determining residual, functional hearing and a response to amplification in a deaf person is crucial. A deaf patient who cannot recognize speech, with effective amplification, at 50 to 60 dB SPL (sound pressure level), (these levels reflect real-life listening levels), is a possible candidate for a CI. Word discrimination should not exceed 50% to 60% with the best possible amplification.

Assessing a prelingually deaf baby/child for a CI poses special challenges. These children should have a severe (PTA: 70-95 dB) or profound hearing loss (PTA more than 95 dB). Neonatal screening makes early hearing assessments possible so that babies of 6 months can be implanted to have the neurobehavioral advantage of the critical period for speech and language development. Auditory stimulation begins in utero (at about 24 weeks gestational age), peaks at about 6 months, with the fastest growth during the first 3 months of life according to Grantham-McGregor et al, 2007:61.

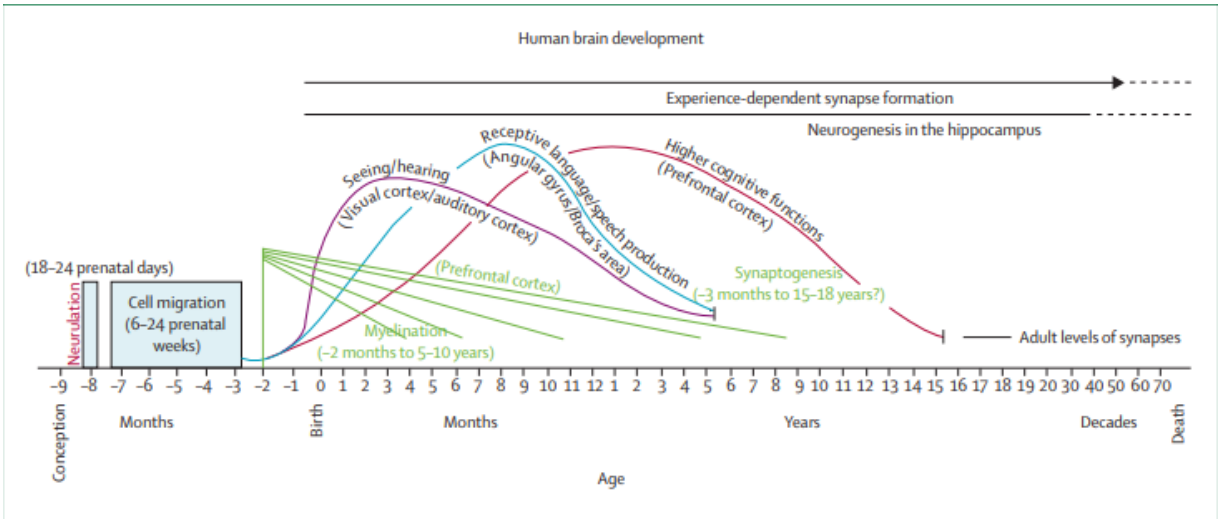

Figure 4: Human Brain Development (Grantham-McGregor et al, 2007:61)

Parents of newly diagnosed deaf children must decide whether their child should receive a CI and give informed consent for the procedure to be carried out. Informed consent is based on the moral principle of respect for autonomy, but in this situation the child is incompetent and the ideal surrogate decision makers are the child's parents.

Beauchamp and Childress (2013:124) define informed consent as consisting of five elements: disclosure, recommendation, understanding, decision and authorization, but with two preconditions: competence and voluntariness. Parents of deaf children should be competent to decide on behalf of their child and they will surely do it voluntarily. They must however be fully informed about the options available for their child to be able to communicate. They must understand the implications of their choice to implant their child, or to teach him/her Sign language. They must be informed about the risks involved in each decision as well as the long-term commitment necessary for each decision. If they decide to have their child implanted, they should be informed about the risks of the operation as well as the possible results of the CI. This is an especially important decision to take on behalf of their child, as it will have consequences and influences on the personal, social and cultural lives, not only of the implantee but also the whole family.

Wever (2002: 85) interviewed parents of 16 children who received CIs and parents of 7 children whose parents decided against a CI. He found that the parents used the "best-interest" principle for their children to decide whether to have a CI or not (Wever, 2002:416).

Parents of a deaf child will be confronted by 2 different groups that offers 4 options: Deaf culture, sign language/Deaf culture until the child is 18 years old and can then decide for

him/herself, CI and sign language and then the child can decide for him/herself at 18 years of age whether to continue wearing the CI, or CI. Each option has its own unique advantages and disadvantages.

Deaf culture. Proponents of this option (only sign language for communication and being part of the Deaf culture) view deafness as an advantage and not as a disability. Deafness admits the child to the rich and unique culture of the Deaf. They see CIs as a threat to their culture and parents of a deaf child are obligated to allow the child to be incorporated in the Deaf culture. For hearing parents (90% of children born deaf are born to hearing parents) this option means they will have to learn sign language as well, to be able to communicate with their child. Also, according to Levy (2002a:148) "One is not born into a culture but socialized into it". He concludes that the hearing parents of a deaf child are under no obligation to support the Deaf culture by assimilating their child into its culture. McCormick (2010:1188) states that the dwindling Deaf culture is not a good argument against CIs. He agrees with Dena Davis (Davis, 1997:7-15) who says: "the primary argument against deliberately seeking to produce deaf children is that it violates the child's own autonomy and narrows the scope of her choices when she grows up; in other words, it violates her right to an 'open future'".

Sign language, later CI. Supporters of the Deaf community often offer this option as a compromise between sign language and a CI. It is however not in the best interest of the child because of the poor results with speech development after being deaf for 18 years. The parents will also have to learn sign language.

CI and sign language. This is the "ideal situation" according to Humphries et al (2012:202) because the child is exposed to both types of communication and cultures and can later in life decide which culture he/she wants to belong to. This is, however, not a very practical option as the child with a CI needs intense rehabilitation which involves the parents as well, leaving little time to learn a new language.

CI. If the child meets the criteria to be a candidate for a CI and the parents are prepared to be involved in the rehabilitation process and they (or their medical aid) can afford it, this is the best option for the child. If, later in life the child wishes to become part of the Deaf community and use sign language, he/she can become a nonuser simply by removing or not wearing the external part of the CI.

After implanting a patient with a CI, he/she must have access to rehabilitation which consists of mainly Audiology and Speech therapy. Initially, after implantation, this rehabilitation is

intensive, but later only maintenance is necessary although it is a life-long commitment. For a child to optimally utilize a CI he/she must have the appropriate, and flexible, educational placement.

The indications for a CI have broadened as results with CIs have improved. Children with a significant low frequency residual hearing can benefit from a CI using a short electrode array to only stimulate the basal part of the cochlea that codifies for higher frequencies. Bilateral CIs improve the localization of sound as well as listening in noisy environments, therefore it is done as a single procedure or two different procedures (Vincenti et al, 2014:4-5).

A CI unit may be faced with the dilemma of having to decide whether, if resources are limited, a 6-month-old child (with congenital deafness) or a 30-year-old adult (with acquired deafness) should be implanted. Distribution/Rationing of resources plays an important role in these decisions. Landman et al (2000:47) see resource distribution happening on a Macro and Micro level. Macro-allocation policies distribute resources at national and regional levels, whereas micro-allocation distribute resources to patients at the point of treatment to generate the most possible good. Unavoidable rationing justifies medical utility. Implanting a baby at 6 months with a CI should give the child at least 70 years of hearing (opportunities), compared to 40 years for the adult; therefore, if only one device is available, the baby should receive it.

Govaerts (2016:75) morally criticizes the usual criteria for receiving a CI as they deny many people the advantage of a CI because of bureaucratic restrictions set by these criteria. He proposes a more liberal application of the present criteria and the healthcare purchaser and society must decide whether more CIs are financially justified.

2.7 Team

Accessing a patient for a possible CI is a multidisciplinary process and the rehabilitation after the surgery also requires a team approach. Pre-operatively the patient must be evaluated by an audiologist, speech therapist, occupational therapist, ophthalmologist, psychologist, pediatrician, surgeon and anesthetist. Scans (MR and CT) of the patient's ears (temporal bones) are necessary to plan the surgery. All the members of the team must, after taking all the factors of a specific patient into consideration, agree that the patient is a candidate for a CI. The parents

of a child or an adult patient will then be offered the option of a CI. Post-implantation the audiologist and speech therapist coordinate the rehabilitation process.

2.8 Surgery

Once the patient has been identified as a successful candidate for a CI, he/she or the parents will be informed about the surgery and possible complications. The patient or the parents of a child will be informed about the different devices available, their advantages and disadvantages, and they are then allowed to choose the device to be implanted. Implanting the receiver and electrode array is done under general anesthesia, therefore the patient will also be evaluated by an anesthetist. Postoperative complications include, according to Gleeson (2008:3654):

- **Facial nerve stimulation** – between 7% and 25% of patients have this complication but it can be controlled by device reprogramming in virtually all patients,
- **Vertigo** – 74% of patients have vertigo or imbalance, but it is treated effectively with vestibular therapy,
- **Device failure** – this happens in 3,7% of patients but reimplantation effectively treats this complication,
- **Meningitis** – the incidence of this complication in a CI patient is the same as in the general population, i.e. 10 cases per year per 100 000. Candidates should receive vaccination against strains of pneumococcus, which is the most common causative organism.

Various parameters are used to measure the outcome or benefit of CI. Improvement of communication skills can be measured by testing hearing levels, speech perception and speech production. Using the HINT (Hearing-in-Noise Test) to test speech perception, scores of less than 40% preoperatively, improved to at least 75% postoperatively (Waltzman and Roland, 2014:171). She also submits the following predictors of benefit in adults:

- **Duration of Deafness** – a long period of preoperative deafness is a predictor of poorer outcome/success with a CI. For children, the concept of Neuroplasticity (Waltzman and Roland, 2014:38) requires implanting a child as soon as possible.

- **Age at Implantation** – younger adults have better speech perception scores than older patients, but this is controversial.
- **Design of the Device** – the number of active electrodes as well as the design of the electrode array have an effect on the benefits gained from a CI. With more active electrodes, more spiral ganglia can be stimulated. A softer electrode array causes less damage to the residual hair cells so that speech perception is improved by having electric and acoustic stimulation in the same ear.
- **Duration of Use** – during the first 6 to 9 months the patient will experience a steady improvement in speech perception.
- **Residual Hearing Preoperatively** – some studies have shown that a greater amount of preoperative residual hearing equates to better postoperative speech perception.
- **Residual Hearing in Contralateral Ear** – bimodal stimulation, i.e. a hearing aid in the one ear and a CI in the other, improves speech perception.
- **Choice of Ear for Implantation** – whether the better or poorer hearing ear is implanted makes no difference to the postoperative speech perception.
- **Device Failure** – revision surgery restores speech reception to levels achieved when the previous device was still functional.
- **Bilateral CIs** – patients with bilateral CIs have better speech reception and sound localization than patients with only one CI.

Approximately 1,2% of implanted patients in South Africa do not use their devices according to Emmett et al (2015:1359).

2.9 Recommendations

If a child is born with a severe or profound hearing loss and, after all the assessments, is found by a CI-team to be a candidate for a CI, the implant team should inform the parents of the child about all the options available for their child. The CI-team may, however, recommend a cochlear implant if asked by the parents. The same applies to peri- and postlingually deaf children and adults. For the best possible results with a CI the time between the diagnosis of the deafness and the implantation should be as short as possible. If the postlingual deafness was caused by meningitis, the cochlea ossifies within a few months which makes a CI impossible. Therefore, it is crucial to have these patients evaluated for a CI as soon as possible.

2.10 Case Study 2

Byrd et al (2011:1800) present the case of an 8-month-old congenitally deaf baby who has an older brother with the same genetic condition. Their parents have normal hearing, but both grew up with hearing impaired parents, have hearing impaired relatives and are sign language interpreters. The parents wish to incorporate both their children into the Deaf community with sign language as the only way of communication, and they are thus opposed to cochlear implants. In Michigan, the Child Protective Services (a state funded organization) may intervene to preserve the best interest of the child. Michigan State Law requires health care workers to report any case of suspected child abuse or neglect. Hearing parents who deny their child the opportunity to hear and thus limit their child's academic, professional and social potential, can be seen as neglecting and harming the child and should therefore be reported to the Child Protective Services. It is imperative that the parents must be informed of all the advantages of a CI as well as the possible disadvantages. The health care worker should recommend a CI and if the parents still refuse it, the health care worker is obliged to report the case to the Child Protective Services.

The medical center's ethics committee reviewed the case (Byrd et al, 2011:1803) and concluded that implantation against parental wishes was not ethical. The legal expert of the centre was also consulted, and she could not find enough legal infringements to warrant a report to the Child Protective Services.

In this article no mention is made of cost implications for the parents and therefore I assume the cost of a CI will be covered by medical insurance. Rehabilitation after a CI is time consuming and can be very difficult, but it is easier for hearing parents of a deaf child. If the hearing parents are also fluent in Sign language, like in this case, it will be of immense benefit to the child, as he/she will be exposed to both languages and cultures. The parents should therefore be strongly advised to have a CI for their child and if they still refuse, like in this case, referral to an ethics committee is justified. The ethics committee should endorse the recommendation of a CI and warn the parents that denying their child a CI may be seen as child neglect and may therefore be reported to the Child Protective Services. But forcing the parents to have a CI for their child against their will, will also have a detrimental effect on the rehabilitation of the child and eventually a poor result with speech development. The morally correct thing to do is therefore to strongly recommend a CI but to allow the parents to make

the final decision. This case illustrates the measures health care workers should take to protect a child's best interests, as parents cannot claim to have unrestricted rights to decide for their children, but they are entitled to raise their children the way they want to.

Chapter 3: Newborn Hearing Screening

3.1 Introduction

The incidence of permanent congenital or early-onset hearing loss is approximately 6 per 1000 live births in developing countries and 2 per 1000 live births in developed countries (Olusanya, 2012:654). Early diagnosis of a hearing loss is the initiating step for any Early Hearing Detection and Intervention (EHDI) program and is made by using Newborn/Neonatal Hearing Screening (NHS). The goal of early detection is to minimize the time between the diagnosis of the hearing loss and the management/treatment thereof. Early treatment minimizes auditory deprivation and maximally stimulates auditory development which results in linguistic competence and literacy development. If the auditory system is not stimulated during this sensitive period, normal cortical development does not take place and the brain re-organizes itself to use vision instead of hearing. Language development can be delayed by 2 to 4 years if a hearing loss is detected in an infant older than 6 months (Yoshinaga-Itano et al, 1998:1169). Where NHS identifies an infant with a hearing loss, it gives the parents more time to be better informed about the options available to treat their child.

The World Health Organization (2010:30) states: “The ideal is for all countries to work towards the universal physiological hearing screening of all neonates”. They suggest that all neonates should be screened by 1 month of age, for those who do not pass the screening test a diagnostic audiological evaluation should be completed by 3 months of age and intervention (audiological, medical and educational) should be offered to all infants with hearing loss before 6 months of age (so-called 1-3-6 model).

3.2 Definition

The World Health Organization (WHO: Cancer Screening) defines screening as “the presumptive identification of unrecognized disease in an apparently healthy, asymptomatic population by means of tests, examinations or other procedures that can be applied rapidly and

easily to the target population". It is a process that begins with informing and inviting the target population to participate and ends with treatment of the relevantly identified persons.

Andermann et al (2008:318) suggest the following criteria for screening:

1. the screening program must address a known need.
2. the purpose of screening should be defined at the beginning.
3. there must be a specific target population.
4. there should be scientific proof of the screening program's effectiveness.
5. the program must coordinate education, testing, clinical services and program management.
6. quality assurance should provide mechanisms to minimize potential risks of screening.
7. the program must make sure that informed choice, confidentiality and respect for autonomy are upheld.
8. the program must promote fairness and be accessible to the whole target population.
9. the program must be evaluated from the beginning.
10. the potential benefits of screening should be more than the harm.

It is possible for NHS to comply with all the above criteria: there is a recognized need for NHS, it is possible to define the objectives for NHS, and there is a target population (all newborn infants). NHS has a sensitivity and specificity of more than 90%. It is possible to integrate education, testing and clinical services, and potential risks can be minimized. Fairness in access to the NHS program can be ensured, and the program can be evaluated. Overall benefits outweigh the possible harm. Ensuring that NHS is an informed choice of the parents, that it is treated with confidentiality and respecting the parent's autonomy, can be challenging.

Targeted hearing screening, i.e. screening only high-risk infants e.g. those in the neonatal intensive care unit, misses approximately 50% of infants with hearing loss (Kanne et al, 1999:28). Therefore, Universal Newborn Hearing Screening (UNHS) i.e. screening all newborn infants, is the ideal approach to achieve the goals of EHDI.

3.3 Physiology

Otoacoustic emissions

The outer hair cells in the cochlea emit low intensity sound – called otoacoustic emissions - in response to audible sound. These otoacoustic emissions (OAEs) can be measured with a probe in the ear canal (Gleeson, 2008:3276). There are four types of OAEs: spontaneous, transient evoked, distortion product and stimulus frequency OAEs according to Gleeson (2013:3277). The last three types are Automated Otoacoustic Emissions (AOAEs) and depends on the type of sound used to stimulate the cochlea. Transient-evoked otoacoustic emissions (TEOAEs) use clicks or tone bursts presented to the ear via a transducer fitted in the ear canal. Distortion-product Otoacoustic Emissions (DPOAEs) are generated by stimulating the cochlea with two continuous pure tones/sounds. Stimulus frequency OAEs (SFOAEs) use a continuous pure tone to stimulate the cochlea. DPOAEs can predict frequency specific hearing sensitivity but as this is not critical for screening, TEOAE is mostly used in newborn hearing screening programmes. TEOAEs are simple, fast and cheap (Kanne et al, 1999:31) but they assess only a small part of the auditory system (cochlea) and are negatively influenced by vernix in the ear canal, middle ear fluid and a noisy environment (Kanji and Khoza-Shangase, 2016:1).

Auditory Brainstem Response

The Auditory Brainstem Response (ABR) measures the entire auditory pathway electrophysiologically (Gleeson, 2008:3280) by using three scalp electrodes, similar to an Electro-encephalogram (EEG). The cochlea is stimulated, while the baby is sleeping or sedated, using a series of clicks. An automated version (AABR) was designed for screening purposes. Although an AABR assesses the whole auditory system, it requires more expertise to conduct, is more expensive and takes longer to perform (Kanji and Khoza-Shangase, 2016:1).

Both tests give a result as “pass” or “fail”. If the infant fails the first screening test, he/she should have a followed-up test. Because of its negative connotation, the term “fail” is replaced by the term “refer”. Screening programmes usually use AOAEs as a primary screening test and if the baby does not pass this test, an AABR is used. If the baby fails the second screening test, he/she must be referred to an audiologist and otorhinolaryngologist for further diagnostic tests.

False positive ("refer") results are possible but will be confirmed or rejected at the follow-up screening as will false negative ("pass") results. The first hearing screening test should ideally be done before the baby and its mother are discharged from hospital, but not later than 1 month of age. The second hearing screening should be done before the baby is 2 months old so that a full diagnostic audiological evaluation can be completed (if necessary) when the baby is 3 months old (WHO, 2010:30). If the baby is diagnosed with a hearing loss, the parents have a few months (at the most 3 months) to decide on treatment for their child.

In 1994 the Joint Committee on Infant Hearing (JCIH) published a statement that endorsed Universal Newborn Hearing Screening. Shearer et al (2019:1) state that at present 43 states and territories in the United States have passed laws enforcing Newborn Hearing Screening. They suggest that programmes for NHS should also include genetic screening to diagnose infants who falsely screened negative for a hearing loss and to diagnose genetic diseases in infants who do have a hearing loss (2019:14).

The Health Profession Council of South Africa recommends universal hearing screening of babies in hospitals before discharge or in community clinics at the three-day postnatal visit (HPCSA, 2018:20). The HPCSA endorses OAEs and AABR as technologies for NHS (HPCSA, 2018:21) and suggests rescreening at 6 weeks and confirmation of hearing loss at 4 months to coincide with immunization visits (HPCSA, 2018:22). Khoza-Shangase et al (2017:162) found in a study of the primary healthcare facilities in two provinces of South Africa (North West and Gauteng) that they did not comply with the recommendations of the HPCSA for NHS. They identified budgetary constraints and staff training and staff shortages as reasons for non-compliance.

3.4 Ethical issues in NHS

The first few days after giving birth can be incredibly stressful for a new mother. She expects and wishes for a normal baby and this can usually be confirmed by health professionals after a routine neonatal examination before discharge from hospital. Congenital hearing loss is not a visible disease and can therefore not be diagnosed during a routine neonatal examination. Objective, non-invasive tests (AOAE and AABR) for screening for congenital hearing loss are available and are accepted as normal care of the newborn.

A screening program that incorporates follow-up screening is very reliable with a sensitivity (the proportion of those with the condition that are correctly diagnosed) and specificity (the proportion of those without the condition that is correctly excluded) of more than 90% (Kennedy et al, 2005:661). If a child with a hearing loss is not identified by means of a screening program, the parents will usually become aware of an inability to respond to sound, inappropriate behaviour or speech and language defects, only when the child is between 12 and 18 months old. During this period, parents who suspect that something is wrong with their child, are usually anxious and confused and will visit various health practitioners before the correct diagnosis is made and appropriate treatment initiated. Young and Tattersall (2007:213) interviewed parents of 27 babies born deaf and correctly diagnosed with NHS. They found that the majority of parents (21 out of 27) were emphatically positive about the early diagnosis of deafness in their child.

There are, however, also some risks for the parents and newborn. There will be children, albeit a small percentage, who fail the screening test but do not have a hearing loss and some who pass the test but do have a hearing loss. These results may cause unnecessary anxiety in the parents until a diagnostic evaluation is done, incorrectly assuring the parents that their child is normal, only to find out much later in life that this is not so. Parents of a newborn who failed the screening test may experience negative emotions that can adversely affect the bonding process between parents and child (Olusanya et al, 2006:589).

3.4.1 Risk vs Benefit

Harm

Harm can be regarded as a hindrance to interests in life, health, or welfare.

The English philosopher John Stuart Mill (1806-1873) constructed the so-called Harm Principle in his book *On Liberty* (1859:22) as follows: “That the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others”. His father, James Mill (1773-1836), and Jeremy Bentham (1748-1832) believed that the most important moral principle was that of Utility. This principle requires that whatever we do, must result in the most happiness and the least unhappiness, i.e. a hedonistic consequentialism. John Stuart Mill was brought up in this environment by his father and close

family friend, Jeremy Bentham (Reeves, 2018:3), but in 1826 and 1827 he suffered from depression ("mental crisis" as described by himself) and "….began his long and difficult journey away from a narrow, Benthamite utilitarianism vision towards a profound belief in the inalienable value of individuality and the humanist liberalism that would illuminate his most famous work, *On Liberty* ".

The term *risk* refers to an action or enterprise that holds promise of success, but without any guarantee. It alludes to a possible future harm according to Beauchamp and Childress (2013:230). Risk should further be described according to its probability and severity/magnitude and consequently they suggest the following schema to create 4 different categories:

		Magnitude of Harm	
		Major	*Minor*
Probability of Harm	*High*	**1**	**2**
	Low	**3**	**4**

NHS is a category 4 risk because: it is a non-invasive test, is done quickly while the infant is asleep, is accurate (high sensitivity and specificity), and the possible harm to the parents can be prevented if they are well informed. The term benefit implies a positive value, such as improvement in health. They view the relation between risk and benefit as a ratio between the probability and magnitude of an expected benefit and the probability and magnitude of a possible risk. NHS has a low risk, high benefit ratio. If, however, NHS is not complied with, the probability of harm done to 6 out of every 1000 infants is high, and the magnitude of harm is major, i.e. category 1. This high probability of major harm is brought upon the infant by his/her parents if they refuse NHS. Keeping J.S. Mill's harm principle in mind, it can be argued that NHS should be compulsory for all newborns and is therefore recommended by the Health Professions Council of South Africa (HPCSA, 2018:18), but the implementation thereof can be challenging (Khoza-Shangase et al, 2017: 162).

At birth, every child is assessed using an Apgar score that measures the physical condition of the newborn. It is a mnemonic for: **A**ppearance (skin colour – grey/pale, blue or pink; an indication of oxygenation of blood), **P**ulse (heart rate), **G**rimace response (reflexes), **A**ctivity (muscle tone), and **R**espiration (breathing rate and effort). It is calculated by assigning a value of 0, 1 or 2 to each factor and adding them up to give a value out of 10. This evaluation is done at 1 minute and again at 5 minutes after birth. A score of 7 and more is considered normal and less than 7 means the baby needs medical attention, e.g. suctioning of the airways or oxygen. The Apgar score is thus an indicator for medical treatment.

The effects of congenital hearing loss, the most common congenital sensory impairment, are inevitable and only become noticeable at a time when intervention/treatment does not have the ideal results. To prevent this, NHS should form part of the initial assessment of all newborns, similar to the Apgar score.

3.5 Analyzing ethical issues in NHS

Universally accepted ethical principles should be used to analyze ethical issues in NHS. Beauchamp and Childress devised four principles (autonomy, beneficence, nonmaleficence and justice) and discussed them in their book called *Principles of Biomedical Ethics* which they published in 1979 and edited regularly until the most recent, seventh edition, was published in 2013. Applying only these principles to solve biomedical dilemmas has been criticized by many experts (Page, 2012) but they are usually accepted as a good starting point for analyzing an ethical problem. They can be applied to NHS as follows:

- Parental **Autonomy** – respect the decision of the parents to accept or decline NHS.
- **Non-maleficence** – avoid causing harm to the parents or child.
- **Beneficence** – NHS must benefit the parents and child, or the benefits must outweigh the risks.
- **Justice** – benefits and risks must be fairly distributed and access to NHS must be available to all newborns.

Jonsen et al (2015:3) compares an ethical case with a clinical case where a standardized pattern is used to organize the details of every case: evaluation of the chief complaint, results of the physical examination and laboratory tests that lead to diagnosis and treatment. They propose

a method of four topics to organize facts in an ethical case: medical indications, patient preferences, quality of life, and contextual features. These so-called "boxes" help to sort the information of every ethical case into relevant or irrelevant, and important or unimportant. Their book, *Clinical Ethics: a practical approach to ethical decisions in clinical medicine*, in which they describe this approach, is now in its eighth edition. They believe that most ethical dilemmas can be resolved by weighing the information in each of these boxes and that, viewed together, these boxes create a complete picture of the ethical features of the case. A decision can then be made on how to manage the problem/dilemma. To achieve this, they use Beauchamp and Childress's four biomedical principles:

- **Medical Indications** – the principles of Beneficence and Nonmaleficence.
- **Preferences of Patients** – the principle of respect for Autonomy.
- **Quality of Life** – the principles of Beneficence, Nonmaleficence and respect for Autonomy.
- **Contextual Features** – the principle of Justice and Fairness.

All four topics/boxes with their associated principles must be considered, as together they contribute to a possible/probable solution of the problem. Dr. William Osler (1849-1919), often described as the Father of Modern Medicine, wisely commented more than 100 years ago that, "medicine is a science of uncertainty and an art of probability".

Anantham (2017:23) states that the four-box system will not solve an ethical dilemma on its own, but by correlating ethical principles with facts from the boxes will help clinicians to realize what is ethically important. This system also ensures that clinicians facing an ethical dilemma do not miss something important. He foresees that regular use of this method by clinicians will dispel moral distress and thus be beneficial to our patients.

Sokol (2008:513) used the four-quadrant approach to analyze a case published in Ackerman and Strong's *A casebook of medical ethics* to prove that this approach can guide clinicians to reach morally justified decisions. He views the four-quadrant approach as more practical than the four principles of Beauchamp and Childress although it is useful to combine them if using the methods of specification and balancing of the principles. He regards this approach as typically casuistic because it attends to all the details first in order to finally recognize the primary moral issue. Clinicians should feel comfortable in using this approach (p516) as it moves from concrete facts (medical indications) to more abstract influences (contextual features) which is similar to the approach to a clinical problem: gather as much information as

possible (history, examination, special examinations) and then deliberate on possible treatments.

I find this comprehensive approach structured and practical and will review this approach and apply it to NHS by discussing a case.

3.5.1 Medical Indications/Facts

These are the facts of a patient's physical and/or psychological condition that the physician uses to meet the goals of medicine. The Hastings Centre identifies four goals of medicine: 1) prevention of disease and injury, the promotion and maintenance of health; 2) relief of pain and suffering caused by diseases; 3) care and cure of those with a disease, care for those who cannot be cured; 4) avoidance of premature death and the quest for a peaceful death (Anderson, 2007:407). The principles of beneficence (to improve physical and/or psychological health) and nonmaleficence (prevent further harm or reduce risk of harm) are applicable to Medical Indications/Facts. Sometimes these two principles come in conflict with each other and then it is important to calculate a benefit-risk ratio, for example, treating otitis media in a diabetic patient with a course of steroids but realising it will make control of the diabetes more difficult.

In this quadrant the physician must identify and describe the patient's medical problem as comprehensively as possible, mention the goals of treatment and the situations in which treatment is not indicated, and the likelihood of success of different treatments. After completing this quadrant, the physician can recommend a plan of action based on his/her knowledge and experience and keeping in mind the patient's goals and values. The patient may accept or reject the physician's recommendations according to his/her personal preferences.

It is therefore logical to have Medical Indications as a first quadrant as the results of this quadrant influence the other three quadrants.

Application to NHS

NHS is used to identify congenital hearing loss which, if not diagnosed early (ideally before 6 months of age) and treated appropriately, will result in severe developmental problems later in childhood and disability in adulthood. NHS is very effective with a sensitivity and specificity

of more than 90% and the treatment of the hearing loss (either with a hearing aid or Cochlear Implant) is highly successful. NHS results in avoidance of harm to up to 6 newborns out of 1000 live births. Taking all these facts into consideration, NHS satisfies the principles of Beneficence (early diagnosis of congenital hearing loss) and Non-maleficence (avoiding developmental problems later in childhood) and should therefore be recommended to the parents of all newborn children.

3.5.2 Preferences of Patients

A newborn child's natural surrogates are its parents but more specifically, its mother. The newborn baby is obviously incompetent to make any decision, but his/her surrogate decision maker(-s) must be competent to decide on his/her behalf. Beauchamp and Childress (2013:190) propose the following qualifications for a surrogate decision maker: she must,

1. be competent – be able to understand the situation and the information presented and work out and articulate a preference.
2. have adequate knowledge and information.
3. be emotionally stable.
4. be committed to the incompetent patient's best interests and should not be influenced by those who are not concerned with the patient's best interest.

Buchanan and Brock (1986:26) state that competence is a "threshold concept, not a comparative one" implying a person is either competent, or not competent.

Wever (2002:416) empirically studied parent's reasons for choosing a CI for their children and found them to be highly child-centered and best interest oriented. It is therefore essentially a quality-of-life standard.

A newborn baby's competent mother must give consent to have her baby subjected to NHS.

Beauchamp and Childress (2013:124) define informed consent by separating the concept into two components, information, and consent, with two prerequisites, namely competence and voluntariness. The information component includes disclosure of applicable information, recommendation of an action, and comprehension of the information and recommended action. The consent component consists of a decision and authorization. Buchanan and Brock view competency as an important component of informed consent (1986:26). They also state that

deciding whether a patient is competent, or incompetent is a binary decision, i.e. a patient is either competent or incompetent, he/she cannot be partially incompetent for a specific decision.

3.5.2.1 Disclosure

Jonsen et al (2015:57) recommend that the physician uses the so-called 'subjective' standard to disclose information and not the prudent physician or reasonable patient standards, because the subjective standard is patient specific, i.e. it customizes the information to the patient's needs and understanding. They recommend that disclosure should include:1) the patients present medical condition and the probable consequences if it is not treated; 2) a description of the treatment that might improve the condition which should include a discussion of the risks and benefits of this treatment; 3) alternative options available; 4) a recommendation based on the clinician's clinical judgement and experience. The physician must realize that patients may be distressed and/or distracted and should therefore give information clearly and simply and ascertain whether the patient understands it by inviting and asking questions. The situation in which the patient finds him/herself determines the volume of information given to the patient: in some emergency situations very little information need to be provided, but for elective or nonemergency treatment much more information is required.

Intentional nondisclosure is permissible (Beauchamp and Childress, 2013:127) in an emergency, where the patient is incompetent or forego/waive the information and where the physician uses therapeutic privilege to withhold information. If withholding information from a patient will result in decreased levels of anxiety and stress, it should be done.

Lo (2020: 52-53) states that deception to prevent serious harm to a patient or to restore a patient's autonomy, is acceptable.

The word 'doctor' originates from the Latin verb docēre 'to teach'. Physicians are compelled to teach not only students, colleagues, and nursing personnel, but especially patients. This teaching should educate the patient about his/her medical condition, should be understandable to the patient and help him/her to make an informed decision about treatment.

3.5.2.2 Understanding

Many elements may limit a patient's understanding of his/her medical condition and available options. These include stress and nervousness about the disease, the illness itself or irrationality and immaturity. Information overload and too little information may also prevent understanding. Physicians must also be careful not to present information in a biased way.

3.5.2.3 Recommendation

In the physician-patient relationship, informed consent is characterized by good communication, reciprocal respect and participation that results in shared decision-making. This requires proper disclosure and good understanding of the relevant facts to form a therapeutic partnership that benefits the patient as well as the physician. The physician should recommend a specific intervention, but the patient may accept it or not.

3.5.2.4 Voluntariness

A person acts voluntarily when he/she is not being controlled by another person or condition and can thus act autonomously. Beauchamp and Childress (2013:139) view the manipulation of information conflicting with autonomous decision making.

3.5.2.5 Competence

Disclosure and informed consent assume that the patient is competent and able to understand the information presented to him/her. Jonsen et al (2015:69) prefer to call this ability to process and react to information, decisional capacity or incapacity. They define decisional capacity to give or refuse consent as the ability to understand applicable information, recognize the medical condition and the consequences of its treatment or nontreatment, talk about his/her choice and take part in a discussion about own values compared to the physician's recommendation about treatment options. This definition is similar to that proposed by

Beauchamp and Childress (2013:118) who require three kinds of skills for a patient to be competent: construct a preference, recognize the situation and understand the information and consider all available options and take a decision. A person may be competent or incompetent for a specific situation or task and differently in other aspects of life.

Determining decisional capacity is a clinical decision and should be done while talking to the patient, noting behavior, and talking to third parties who are familiar with the patient (Jonsen et al, 2015:71). Observing inconsistencies, incoherence and confusion in a patient may lead a physician to diagnose dementia, delirium, or encephalopathy. Buchanan and Brock (1986:23) define determination of competency as, "…. a determination of a particular person's capacity to perform a particular decision-making task at a particular time and under specified conditions". Determining a patient's competency should therefore take into consideration the type of decision, when it is made, and under what condition. However, sometimes it can be difficult to clinically decide whether a patient has decisional capacity and then tests for cognitive functioning can be used: the MacArthur Competence Assessment Test (MacCAT-T) (Grisso et al, 1997:1416), or the Aid to Capacity Evaluation (ACE) developed by the Joint Centre for Bioethics, University of Toronto. In some patients, especially when a psychiatric disorder might be present, it can be difficult to determine capacity. In these situations, the opinion of a psychiatrist, neuropsychologist or clinical psychologist should be sought. In determining decision-making capacity, Lo (2020:73) suggests asking questions that satisfy the following headings:1) Does the patient understand the disclosed information? 2) Does the patient appreciate the consequences of his/her choices? 3) Does the patient use reasoning to make a choice?

Delirium, a pathological disturbance of awareness, is characterized by disorientation, distraction, disorganized thinking, inattentiveness or hypervigilance, agitation, or lethargy and sometimes hallucinations. Minor diseases, e.g. cystitis (bladder infection), may cause delirium in the elderly. Delirium may fluctuate: early in the day the patient may be orientated but later in the day he/she can be assessed as confused (so-called 'sundowner syndrome'). Delirium impairs a patient's decisional capacity but during periods of clarity, decisional capacity may be restored.

3.5.2.6 Surrogate Decision Makers

When a patient is unable to communicate his/her wishes for medical care, a surrogate decision maker communicates on the patient's behalf. Buchanan and Brock (1986:49) suggest that we use a set of related principles that constitute a theory of surrogate decision making. They see the following principles as most important:

1. **Ethical Value Principles** – these principles identify the ethical values that should be complied with. They are respect for an individual's self-determination (autonomy), concern for the individual's well-being (beneficence) and distributive justice.
2. **Guidance Principles** – these principles give advice on how decisions should be made and include: best interest, substituted judgement and advance directive.
3. **Authority Principles** – these principles attempt to answer the question: who should make decisions for the incompetent. Although shared decision making is desirable, this principle identifies the dominant decision maker and they are in progressive order: the family, physicians, and eventually the court.
4. **Intervention Principles** – when the person or institution identified under authorative principles is allowed to intervene and take decisions out of the hands of those assumed to have authority to make decisions on behalf of the incompetent.

They admit that these principles contribute to an ideal theory of surrogate decision making, but realistic expectations will inevitably involve compromises (Buchanan and Brock, 1986:50).

Parents, as the natural and preferred surrogate decision makers for their children, should use the best interest standard to decide about their child's health. Children are not yet autonomous, but their potential to become so, deserves respect. Lo (2020:268) suggest the term parental permission, instead of consent, because parents do not have absolute control to deny care for their children, and parental permission must be supplemented with the developmentally mature child's assent.

Although physicians and parents share the decision-making process where children are involved, the physician should use the opportunity to teach the mature child how to take responsibility for one's own health (docere, to teach). Furthermore, the parents should realize their child can show responsibility. In my Ear, Nose and Throat practice I have found that involving a responsible child in the decision to, for example, have a tonsillectomy, results in

that child managing the procedure and postoperative pain much better than the child not involved in the decision making process.

Application to NHS

A newborn baby's natural surrogate is his/her mother who should use the Best Interest standard to decide for her baby. The mother and father must be informed about the benefits of doing a hearing screening on their baby; why it is important to do the hearing screening as soon as possible; that it is not a painful procedure and if the newborn does not pass the first screening test, it is important to do a follow-up screening test. The parents must be supplied with a hard copy of this information, for example a pamphlet, to study at their leisure. She must be approached compassionately because this is a very emotional period in the new mother's life. The health professional/audiologist may strongly recommend NHS, but if the mother has decisional capacity and she refuses the screening, the health professional must discuss her objections to the test and try to persuade her, but if unsuccessful, she must abide by the mother's decision. In the best interest of the child, the health professional is obligated to request that the mother should report any symptoms that might indicate deafness, e.g. no reaction to loud sounds, or delayed or no speech development. A mother who refuses NHS, must be informed that she may still present her child at a later date for a screening test, for example, when she takes her child for immunizations. It must be explained to her that diagnosing and treating a child with deafness during the first year of life has a better prognosis for language development than diagnosing and treating the deafness when the child is three or four years old and cannot communicate (i.e. the child misses the sensitive period for language development because of neuroplasticity of the brain).

3.5.3 Quality of Life

A person's quality of life is highly personal and subjective. It refers to how satisfied a person feels with life, particularly their physical and psychological state of health (Jonsen et al, 2015:111-112). An attempt to define quality of life empirically is that it is a multifaceted model that includes "performance and enjoyment of social roles, physical health, intellectual functioning, emotional state, and life satisfaction or well-being."

According to Jonsen et al (2015:115) the phrase quality-of-life can be used in two contexts: by an individual concerning his/her own experience, or by an observer evaluating someone else's experience. Because quality of life is such a personal and subjective experience, an observer must be very careful not to be biased or prejudiced. The evaluation of quality of life may fluctuate with time, so patients and physicians should not make important decisions when a condition might be temporary.

Lo (2020:35-36) takes the following into consideration when using the term quality of life: symptoms of a disease and the side-effects of any treatment, the patient's ability to perform daily activities (walking, shopping, household chores), the patient's subjective experiences of pleasure, pain and suffering, and the patient's independence, privacy and dignity. Patients with decisional capacity take their quality of life and their duration of life into account when they make health care decisions.

If a patient is incompetent/does not have decisional capacity, the Best Interest standard should be used by the surrogate decision maker. Interests common to all human beings include being alive, being able to understand and communicate their thoughts and emotions, being able to control their lives, being free from pain and suffering and being able to achieve desired satisfactions (Jonsen et al, 2015:118). A surrogate decision maker must modify these interests to best apply to the patient with whom he/she has a personal, intimate relationship.

The ethical principle of Beneficence requires physicians to promote the welfare of their patients and is shaped by the doctor-patient relationship and medical professionalism (Lo, 2020:34). The doctor-patient relationship is a fiduciary (from the Latin word fidere, to trust) relationship as it is anchored in trust in the physician. He/she should act in the best interests of the patient, and regard this as being of greater importance than his/her self-interest, or that of a third party, eg. the hospital. Professionalism implies patient-centered care that respects the patient's autonomy and integrity. In certain situations, it might be necessary for a doctor to override a

patients' decision to benefit the patient (paternalism). If the patient is fully autonomous and well informed, overriding his/her decision is morally impermissible (hard or strong paternalism). If, however, the patient is not autonomous, has decreased decisional capacity or there is doubt about his/her autonomy, it is permissible for a doctor to act in the patient's best interest (soft or weak paternalism).

The concept of best interest may sometimes include the wellbeing of the family, but according to Beauchamp and Childress (2013:173) the best interest of the individual patient should take preference. However, in deciding what is in the best interest for a child, according to Brudney et al (2014:S80) complex situations may arise where the interests of parents, siblings, health professionals, or even society, should also be taken into consideration.

Lo (2020:40) advises using the following approach to promote the best interests of the competent patient: the physician must understand the patient's perspective and address the misunderstandings and concerns and then try to persuade (not badger) the patient. If the patient does not want to follow the physician's recommendation, they must negotiate a mutually acceptable plan of action but ultimately, it is the patient's decision.

Application to NHS

The competent mother, acting as a surrogate of the newborn child, must consider the child's quality of life when making decisions about the child's health care. This is especially important when deciding whether to subject her newborn child to NHS, when this decision will have a profound impact on the rest of the child's life. Screening newborn babies for the presence of a congenital hearing loss will identify up to 6 newborn children out of 1000 births, who can then be treated appropriately to ensure their best interests. If these children are not identified soon after birth, their quality of life will be negatively affected because of poorer results with rehabilitation, either with hearing aids, a CI, or sign language.

The mother's quality of life will also be negatively influenced by a delay in the diagnosis of a hearing loss in her child, because rehabilitation will be more time consuming than if the child had been diagnosed earlier. The mother must also consider the rest of the family, as a deaf child needs special attention from the whole family, to flourish in life. If a child is identified with a congenital hearing loss, rehabilitation is a prolonged exercise for the parents and adds an extra financial burden which may affect the rest of the family.

3.5.4 Contextual Features

The goal of NHS is to diagnose deafness as soon as possible in order to initiate treatment (hearing aid or CI) before the deafness has a negative impact on the child's development. Performing NHS and treating deafness with a CI has implications not only for the parents and siblings, but also for the extended family and eventually the whole community. Decisions to perform NHS and a CI may be influenced and limited by the context in which the decision takes place. Ethical problems concerning deaf children cannot be viewed in isolation as they always affect at least the parents but also the extended family and society. Factors that may influence decisions include: the family, extended family, religion, financial, institutions, for example hospitals and medical insurers, and legislative. The patient-physician relationship, although very private, may be influenced by these external factors which the physician may view as conflicting with his/her primary responsibility to an individual patient. These factors may influence, fairly or unfairly, the patient and/or the physician and therefore it is ethically essential to determine how important these contextual features are in a specific case, for example, in deciding for NHS and treating a deaf child with a CI.

Although the principles of beneficence and respect for autonomy also apply to contextual features, Jonsen et al (2015:167) argue that the principle of Justice is particularly appropriate. They apply the moral characteristic of fairness, a component of the principle of Justice, to contextual features, as it is relevant to interpersonal relationships and arrangements. They define Fairness as a stipulation in relationships that gives each participant what he/she deserves and can reasonably expect.

Beauchamp and Childress (2013:252) describe four traditional (utilitarian, libertarian, communitarian, and egalitarian) and two recent (capabilities and well-being) theories of Justice. Each theory describes a guideline to distributing justice:

1. according to rules that maximize social utility
2. according to liberty rights and a fair free-market system
3. according to principles of fair distribution that which is "good" in a moral community
4. according to equal measure of liberty and equal access to goods of value that every rational person values
5. according to capabilities necessary to thrive in life

6. according to the realization of the central aspects of well-being.

They discuss Madison Powers and Ruth Faden's approach to social justice which is concerned with human well-being and includes six features, 1) health, 2) personal security 3) reasoning, 4) respect, 5) attachment and 6) self-determination. They suggest that the fair-opportunity rule (based on Rawls's egalitarian theory) should be used to avoid discrimination against people who are not responsible for their situation (so-called life's lottery).

A conflict of interest is very often present in the ethics of contextual features but is only unethical if it results in unfair treatment (Jonsen et al, 2015:168). The term "a conflict of interest" is used to describe circumstances where a person might be tempted to do something that he/she is capable of doing, but the action will be inconsistent with what is expected of him/her. Dedication to fairness is the most important way to control conflicts of interest.

Lo (2020:213) defines conflict of interests as: "situations in which there is an unacceptable probability for secondary interests to unduly influence the primary interest". Conflicting interests should be prioritized to advance the patient's interests, but in contrast, in competing interests, more than one interest may have a claim to priority. He proposes the following to manage conflicts of interests (p214): make sure that the patient's interests are the first priority, disclose any conflict of interests, managing the situation might include regulating the physician's actions, or even prohibiting certain actions, for example, pharmaceutical companies that sponsor continuing medical education are not allowed to dictate to speakers what to say. For example, asking a specialist to promote a new product, but forbidding him/her to mention opposition products. Another example: because of the high cost of a CI, the market to supply CI devices is an extremely competitive environment. A company may offer an incentive consisting of covering the cost of the device as well as follow-up consultations for two years after the implantation of their device. The company will then decide how often follow-up consultations will take place, and with whom. The physician's priority (the patient) is now threatened by the company (third party) who decides when the patient will be seen and treated.

Ackerman and Strong (1989:217) state that although a physician's responsibility towards his/her patient should be the physician's priority, conflicts between patients' interests and third parties often create an ethical dilemma in modern medicine. They suggest (p231) that when assessing competing interests, the following should be taken into consideration: 1) that the patient's moral interests might be affected if the physician gives priority to a third party, 2)

that the duties/obligations of the other party towards the patient should be clarified, 3) the probability and the extent of the risk to the interests of the other party, 4) would a change in the physician's commitment to the patient alleviate the risk to the other party? 5) if this altered commitment favoured the interests of the other party, the indirect negative effects might have to be appraised against its positive effects, 6) if a different approach might protect the interests of the other party but not compromise the physician's loyalty to the patient. For example, if a physician has shares in a private hospital where he/she works or have rooms, patients must be made aware of this by, for instance, a prominent notice in the waiting room.

3.5.4.1 Professional-Patient relationship

NHS is performed by an audiologist or properly trained nurse and this person must respect the professional-patient relationship, not only with the baby and its mother, but also with the extended family.

Members of a profession serve the public and profess to be competent, act with integrity and dedication in this service. Health professionals use codes and oaths to publicly state their commitment to the public. The Physician Charter (2002:244) states three fundamental principles for health care professionals and ten professional responsibilities. The fundamental principles are: the primacy of patient welfare, patient autonomy and social justice. The principle of social justice includes the fair distribution of health care resources and the elimination of discrimination.

Swick et al (2006:271-272) argue that the Physician Charter's focus on duties and competence of a physician is not enough and that virtue-based ethics are necessary for an optimal physician-patient relationship. They suggest that professionalism consists of two levels or tiers: basic and higher. Basic professionalism – "doing the right thing well"- is expected of many occupations (auto-repair, carpentry), but higher professionalism – "service that clearly transcends self-interest"- is a characteristic of the medical profession. Higher professionalism applies to those occupations that are a calling and expects the physician to prioritize his/her patient's interests. This higher professionalism is achieved in stages during the early years of medical training and practice and involves an evolution of "self" (Smith, 2005:439).

Smith (2005:440) acknowledges that the dialogue on professionalism was initiated by conflict between Baby Boomers (born between 1946 and 1964) and Generation X (born between 1965 and 1980). Baby Boomers define professionalism in terms of hours worked and total dedication to the profession, whereas Generation Xers believe that caring for themselves and their families is also important. The characteristics of the "new" medical environment (Smith, 2005:441) must: be patient focused, have flexible work hours, reward excellence and not endurance, emphasize physician well-being and life balance, promote seamless team care, expect excellence and total commitment to work, and cherish the joy of being a doctor.

Beauchamp and Childress (2013:37) discuss five virtues applicable to health professionals: compassion, discernment, trustworthiness, integrity, and conscientiousness. They also state (p302) that the obligation of veracity is important because it specifies the principles of beneficence, nonmaleficence and justice.

Lo (2020:175) suggests that different types of doctor-patient relationships are applicable to different physicians, patients, and clinical situations. The types are: paternalism, informed choice and shared decision making. In a study done by Murray et al (2007:191) they found that most patients prefer the shared decision-making model (62%), the minority preferred paternalism (9%) and the rest (28%) preferred informed choice or so-called consumerism. Patients preferred shared decision-making in management of chronic conditions, but in more acute situations many patients prefer the physician to make the final decision. When a patient has a regular doctor, he/she usually experienced shared decision-making, but informed choice was more common when not having a regular doctor (Murray et al, 2007:193). By matching the patient's preferred style of doctor-patient relationship with his own style, a physician respects the patient's autonomy and enhances patient satisfaction and eventual trust in his/her doctor.

It is unethical for a physician to treat a patient in such a manner that the patient does not primarily benefit, but a third party, for example, a hospital, medical insurance or pharmaceutical company does instead.

A conflict of interests may develop when a physician signs a contract with a medical insurer and thereby exposing the doctor-patient relationship to a third party with its own policies and regulations (Jonsen et al, 2015:170). Policies that were fairly and justly produced may compel a physician to compromise the interests of his/her patient.

If the relationship between a physician and nursing professional or students is not synergistic, so-called "moral distress" may ensue which is defined as "…when one knows the right thing to do but institutional constraints make it nearly impossible to pursue the right course of action" (Jonsen et al, 2015:171). Interpersonal and institutional measures must be implemented to avoid this.

A physician must balance duties to his/her own family and personal well-being, so that it does not interfere with the doctor-patient relationship. Smith (2005:440) views the importance that Generation X physicians attach to family life and personal well-being as a positive factor. Medical students should be taught how not to compromise the doctor-patient relationship with personal duties and there are programs available to educate professionals who find this difficult to achieve.

3.5.4.2 Other Interested Parties

In any clinical relationship the patient and the physician should be the principal parties, but many other parties may influence this relationship, for example, the patient's family, medical insurers, hospital administrators, employers, and pharmaceutical companies. Justified interference in the doctor-patient relationship by these other parties raises ethical questions.

Family and friends of the patient. The specialty of family medicine accepts that in all clinical cases, elements that both cause the disease and may cure the disease are present in the personal relationships the patient has with family or friends (Jonsen et al, 2015:175). They provide emotional support for the patient, act as a surrogate for the patient if he/she is incompetent, but also assist the physician by giving collateral information relevant to the patient's disease. In some cultures, the family will take important medical decisions on behalf of the patient and this must be respected by the physician. The astute physician uses the family to the advantage of his/her patient.

3.5.4.3 Confidentiality

Information given by a patient to a physician is confidential and should not be made available to a third party unless requested by the patient. This respects the autonomy of the patient and keeps the doctor-patient relationship private. Technological improvements in information storage, retrieval and access may threaten the patient's and physician's control of sensitive information. Using diagnostic codes, for example, ICD10, that are available to third parties, like hospitals and/or medical insurers, may jeopardize confidentiality. Sick leave certificates should only divulge to the employer what the patient permits.

Confidentiality is, however, a prima facie ethical obligation as a third party may need to have access to confidential information. The principle of Beneficence allows this disclosure if the patient will benefit from it and if other person/persons will be harmed by not disclosing confidential information, the principle of nonmaleficence warrants the disclosure.

3.5.4.4 Financial factors

The financial impact of interventions on a patient's life must be taken into consideration by the physician and therefore the patient must be informed of the costs to be able to decide what is best for themselves. The costs of alternative treatment must also be discussed with the patient as most patients are not able to evaluate medical efficacy compared to cost. When doing a NHS, the audiologist must discuss the cost of the test with the parents, and if asked, also the cost implications of further audiological tests and a possible CI.

3.5.4.5 Allocation of scarce health resources

Scarce health resources should not be spent on patients who will not benefit, but this must be set out in policies drawn up by institutions and not decided at the bedside, so-called "bedside rationing" (Jonsen et al, 2015:196). Physicians should be involved in setting guidelines and policies for micro-allocation and not only health care administrators, because physicians can supply clinical information that might justify exceptions to general rules (Lo, 2020:228).

Hospitals wanting to draw up policies for doing NHS, should consult with an audiologist and/or otorhinolaryngologist.

3.5.4.6 Religion

Religion plays an important role in many people's lives as it reflects their fundamental values and identity. A physician should not try to change a patient's beliefs or judge whether they are correct but must try to understand how religion affects the patient's decisions (Lo, 2020:74). Religion is based on faith, therefore rational arguments and empirical studies are unlikely to change people's beliefs. During periods of sickness and death, religion can be invaluable. Religion in clinical ethics is complicated as it influences decisions made by the patient and the physician (Jonsen et al, 2015:209). Meador (2009:751) states that it is a challenge for medical education to teach physicians to understand and appreciate the different cultural and religious perceptions of illness and treatments. He suggests (p753) that this should be part of primary medical education and of continuing medical education as a sensitivity and curiosity about our patient's religious values will result in good clinical care.

3.5.4.7 Law in Clinical Ethics

Professional ethical codes urge professionals to obey the law, but relevant legal issues seldom solve ethical problems (Jonsen et al, 2015:212). Health professionals must be able to recognize potential legal problems in a clinical ethical case and then consult with a person who is familiar with the law in bioethics.

3.5.4.8 Clinical Research

Modern medicine needs research to achieve better results for patients and society, but to use patients for clinical research when they are not aware of it, is legally and ethically impermissible. A conflict of interest may develop if the researcher is also a physician: he/she has an obligation to patients but also to perform accurate research in accordance with research

protocols. Therefore, it is important to realize that research and treatment are two separate entities. The physician's primary obligation is to the patient and not to the research. Several documents, for example, the Nuremberg Code (1947), the Helsinki Declaration (1964), and the Belmont Report (1979) declare that clinical research must be guided by ethical principles (Jonsen et al, 2015:215). One of the functions of an Institutional Review Board (IRB) is to determine whether ethical principles have been applied in the setup of a research study.

New approaches to diagnoses and treatments are constantly being developed, so-called Innovative treatment. Jonsen et al (2015:216) states that physicians may use innovative treatment cautiously only if it has been discussed with knowledgeable colleagues, a risk/benefit ratio has been determined as accurately as possible and the patient has given informed consent. An IRB may also be approached for guidance. Innovative treatment must however not be discouraged, otherwise there will be no advances in medicine, for example: House encountered severe criticism (House, 2013:89) when he did the first cochlear implants on children but now our aim is to implant children at 6 months.

If the results of a NHS are intended to be used in research, it must be discussed with the parents and consent obtained.

3.5.4.9 Public Health

Public Health is defined as the science of protecting the safety and improving the health of communities through education, policy making and research for disease and injury prevention. Education of the public includes encouraging preventative care, healthy lifestyles, and warning of health risks (Jonsen et al, 2015:225). Public Health may influence clinical care. For example, protecting the public from communicable diseases may threaten medical confidentiality and patient autonomy. Furthermore, immunization programs may not be made compulsory as this endangers the autonomy of patients.

Resources for doing NHS should form part of the Public Health budget. Considering the cost-effectiveness of NHS and CIs, it can be expected of the state to fund universal NHS.

3.5.4.10 Organizational Ethics

Clinical care usually involves institutions as patients need to be hospitalized, are members of health plans or medical insurance. Clinical decisions and ethics must be entrenched in these institutional structures and policies. Physicians working for an institution, for example, the army, police, prisons or industry, may experience a conflict of interest especially when ethical issues about confidentiality appear, but Jonsen et al (2015:231) advises that such a conflict must always be resolved to the advantage of the patient.

Ethics committees or ethics consultants may be approached by the patient or physician if an ethical dilemma emerges in a clinical situation (Jonsen et al, 2015:233). Members of an ethics committee should come from various disciplines in healthcare in order to have a variety of opinions. Kling (2019:240) quotes Lo from the 4th edition of his book Resolving Ethical Dilemmas as saying: "an interdisciplinary ethics committee sends an important symbolic message to the hospital: Ethical issues are the business of everyone who cares for patients, and clinicians can learn to resolve ethical dilemmas." It is essential that patients and their families are made aware of the existence and functions of such an ethics committee. The opinions of an ethics committee or ethics consultant should be given as recommendations only, and not be prescriptive. These opinions, together with their explanation, must be written in the patient's medical record to avoid misunderstanding and to show accountability (Lo, 2020:129). The attending physician, however, has the authority to follow the recommendations of the ethics committee or not, but in doing so must also act ethically.

Ethical dilemmas may develop in doing NHS and CIs as demonstrated in Case Studies discussed in this document.

Application to NHS

The principle of Justice has a major influence on NHS. By identifying and treating deafness early it promotes social utility (utilitarian theory), the fair distribution of "good" in the community (communitarian theory), gives the newborn access to a valuable commodity (CI) (egalitarian theory), give the deaf newborn the capability (hearing) to thrive in life (capability theory), and ensure the newborn's well-being (well-being theory) by treating deafness as soon as possible. NHS is able to identify deaf children early so that the fair opportunity rule may be

applied to avoid discrimination against children who are not responsible for their condition (life's lottery). The health professional who performs NHS must always respect the professional-patient relationship when he/she approaches the newborn's mother with the option of NHS, keeping in mind that this is a very emotional time in every mother's life. The person performing NHS must be aware that in some cultures, supernatural forces are believed to be responsible for deafness and it should be treated with medicinal plants or animal fat (Olusanya, 2012:655). The health professional must accept that the new mother may be influenced by her family not to subject her child to NHS and therefore the family should also be well informed. The result of NHS is confidential and should only be made available to the surrogate decision maker, i.e. the child's mother or father. The new mother must be informed about the cost of NHS. Most children are born in a maternity ward which is part of a hospital that may have policies regarding Newborn Hearing Screening.

3.6 Case Study 3

Mrs. V. was a 30-year-old owner of a private gymnasium and is also an instructor there. This was her first pregnancy and ultrasound examination showed non-identical, female twins. She was booked for an elective Caesarian section, indications being a first and multiple pregnancy. When she was admitted for the Caesarian section, she was informed by the admission staff that the hospital had a policy to do Newborn Hearing Screening on all babies unless the mother specifically requested that it should not be done (opt-out policy). An audiologist does the NHS and the cost will be covered by her medical insurance. She and her husband not only consented to NHS but were very positive about the procedure because her brother had a congenital, genetic deafness and received a cochlear implant. Her husband worked on an offshore oilrig from which he had sporadic radio communication with the mainland. He could be present for the Caesarian section but had to go back to the oilrig two days after the twins were born. The Caesarion section went well and two healthy baby girls were born, but two days after the twins were delivered Mrs. V. experienced frequent mood changes, felt anxious and irritable and could not stop crying. A psychiatrist evaluated her and made the diagnosis of "Baby Blues". The Psychiatrist advised her to rest as much as possible, accept help from family and friends, contact other new mothers, make time for herself and to avoid alcohol which can make mood swings worse.

When the audiologist approached Mrs. V. three days after the delivery to do NHS on the twins, she told her that if a baby did not pass the first screening test, it was very important to do a follow-up screening test at six weeks, when the pediatrician saw them for a routine follow-up. Mrs. V. told the audiologist that if one of the twins did not pass the NHS, it would increase her anxiety and therefore she declined the NHS. The audiologist could not get hold of Mrs. V.'s husband as he had already left for the oilrig. Mrs. V.'s brother felt that NHS was unnecessary because, although he had received a CI, he was a nonuser and preferred sign language. If one or both twins were deaf, Mrs. V.'s brother saw it as God's will that they should develop with the help of sign language.

The audiologist found herself in a conflicting situation because Mrs. V. and her husband gave consent for NHS at admission, but now Mrs. V. refused the screening test which the audiologist viewed as especially important in the twins, as their uncle had been born with a genetic deafness. The audiologist could not speak to Mrs. V's husband because he had already left for the oilrig and could not be contacted.

3.6.1 Medical Indications/Facts

Twins can develop from a single fertilized egg cell (monozygotic or identical) or from two egg cells that are fertilized independently by two different sperm cells and implanted separately in the uterus (dizygotic or non-identical). Non-identical twins thus have different genetic compositions. The incidence of non-identical twins is 6 to 14 per 1000 births, and of identical twins 3 per 1000 births.

Genetic mutations are responsible for 50% of congenital deafness and if there is a family history of deafness, this figure is higher. NHS is a very accurate method of early detection of any hearing loss, with a sensitivity and specificity of approximately 90%. Early diagnosis of deafness is crucial to start treatment for the best possible developmental outcome; therefore, the WHO suggests the 1-3-6 model: all newborns to be screened for hearing loss by 1 month of age, diagnostic hearing tests done by 3 months and treatment started by 6 months of age.

Having a CI after being deaf for longer than 12 years has an extremely poor prognosis for usable hearing.

The levels of the female reproductive hormones, estrogen and progesterone, drop dramatically after delivery of a baby to reach normal levels within 3 days. Multiple births and a weak support system for the mother are some of the risk factors for developing “Baby Blues”. This condition is quite common, especially after a multiple pregnancy and if there is a weak support system for the new mother. If not treated, “Baby Blues” may lead to Postpartum Depression (PPD) usually within two to three weeks after delivery. Postpartum depression is associated with chemical, social, and psychological changes after childbirth. PPD may be treated with an antidepressant that does not enter breast milk but may only improve symptoms in a few weeks or months.

3.6.2 Patient Preferences

Mrs. V. was the obvious surrogate decision maker for the twins, but if she was incompetent the next person was their father, and if he was not available the next family member was their uncle. When the audiologist approached Mrs. V. for permission to do NHS on the twins she was suffering from “baby blues” and refused the screening and the audiologist could not get hold of her husband. Mrs. V's brother viewed that NHS was unnecessary because even if it did indicate a hearing loss in one or both of the twins, he thought they should learn sign language and that when they were 18, they could decide themselves whether they wanted a Cochlear Implant or not. He also did not want to interfere in ‘God’s will’ and if one or both twins were deaf, it would not be a disability, but a character trait.

The audiologist faced an ethical dilemma: does she comply with Mrs. V’s consent for doing NHS given when she was competent, or does she accept the uncle as the next available surrogate decision maker as she could not get hold of Mrs. V’s husband. The uncle, however did not want her to do a NHS. She wanted to delay the screening for a few days but after discussing the treatment for “baby blues” and the possibility of developing postpartum depression with the psychiatrist, she realized Mrs. V. might only be able to give consent after 3 months. The possible delay in diagnosing a genetic deafness concerned her as she was aware of the poor prognosis if treatment was delayed. She considered doing the NHS without consent as Mrs. V. had not refused the NHS at admission when she was competent but was unsure how to handle the situation if one or both twins failed the screening test. Doing the NHS against the wishes of the mother would not be unethical, because she would act as a surrogate decision

maker for the incompetent mother and babies, and she would be using the principles of best interests for the babies. The parent's consent for NHS when she was admitted to hospital, when the mother was competent, can also be viewed as an advance directive which the audiologist should adhere to. If one or both twins failed the NHS, the audiologist should report this to the father and not the mother, to avoid aggravating the mother's anxiety.

3.6.3 Quality of Life

If one or both twins are not diagnosed with deafness early and treated accordingly, their quality of life will be negatively affected because they will grow up in a household with other members not fluent in sign language. Diagnosing and treating deafness later in life carries a poorer prognosis than early diagnosis and treatment and this will also impact on their quality of life.

Mrs. V.'s quality of life will be negatively affected if one or both of her children is/are diagnosed with deafness later in life as the rehabilitation will be more demanding than with early treatment. Not knowing whether one of her children is deaf may also interfere with the bonding process. If only one of the twins is diagnosed later with deafness and needs intensive rehabilitation, it will negatively affect the other child's quality of life. Diagnosing and treating deafness later in a child's life has a poorer prognosis for speech rehabilitation; therefore, even if the mother changes her mind and present the twins for a hearing screening at one of the immunization visits, it is still better than waiting until lack of speech is noticeable, usually at two to three years of age. The mother is entitled to change her mind, but she must realize that the time available to optimally utilize rehabilitation, is limited.

3.6.4 Contextual features

The hospital where Mrs. V. was admitted, has a policy of doing NHS on all newborns unless the parents chose not to have it done, the so-called opt-out policy. When she was admitted she chose not to opt-out and in fact felt positive about NHS. Mrs. V.'s brother was a non-user of a CI and therefore could not see any urgency in doing NHS and his religious convictions made him refuse NHS. The audiologist should explain to him the benefits of knowing early in a child's life whether he/she is deaf and starting treatment as soon as possible.

3.6.5 Recommendations

When the audiologist approached Mrs. V. for consent to do NHS, Mrs. V. did not have decision-making capacity, but when she was admitted to the hospital and decided not to opt-out on the hospital's policy of doing NHS on all newborn babies, she was able to make an informed decision and she was competent. The hospital policy was known to the audiologist, who also knew that Mrs. V. had not opted-out. However, the only other available family member who could act as a surrogate decision maker was Mrs. V's brother, who refused consent for doing NHS. Should he still refuse, even after the audiologist had explained the importance of NHS, the audiologist should ask the opinion of the ethics committee of the hospital. The ethics committee should advise the audiologist to go ahead and do the NHS, as it is a test with a low probability of harm and a high benefit ratio and the audiologist would be acting in the best interests of the twins by using the advance directive given by the parents when the mother was competent.

If one or both the twins fail the first screening test, the audiologist should again try to contact Mrs. V.'s husband to explain about the importance of doing a follow-up screening test, a month or six weeks later during the immunization visit. If she cannot contact the husband, she should respect the mother's reasons for not doing NHS, i.e. the results might increase her anxiety, and not inform her about the results (complying with the principles of beneficence and nonmaleficence). Nondisclosure of information is permissible because the mother stated that knowledge of the result of NHS would increase her anxiety. The audiologist is obligated to inform the pediatrician, who will perform the routine 6-week follow-up examination of the twins, about the abnormal result, and impress on him/her to refer the patient, who did not pass the NHS, for an audiological assessment. It is the responsibility of the audiologist to follow-up the child with the abnormal NHS in accordance with the concept of higher professionalism, put forth by Swick et al (2006:271-272).

3.7 Conclusion

Newborn Hearing Screening is a highly effective test for the early diagnosis of congenital deafness. It is a procedure that causes little discomfort to the baby and should not make the mother anxious, if she had been well informed. Giving consent for this procedure is probably

the first, particularly important decision a mother, as the surrogate decision maker of the newborn baby, takes. It is an accurate test for hearing loss which can then be treated promptly and effectively to minimize the harm of deafness (disability) on the baby, and therefore complies with the principles of Beneficence and Nonmaleficence. It is also one of the first gestures of goodwill society can bestow on a newborn child and it can be argued that it is not only due to the newborn, but also that the newborn is entitled to be fully evaluated, according to the principle of Justice.

NHS satisfies all the theories of Justice, i.e. Utilitarian, Libertarian, Egalitarian, Communitarian, Capabilities and Well-Being theories. NHS ensures maximum utility/welfare for the newborn baby, its parents and society and respects individual liberty rights owed to the newborn baby by society. The most vulnerable newborn baby deserves more medical attention and all newborns should be treated equally and therefore universal NHS is justified. Diagnosing and treating deaf children promptly will be a social and financial benefit to society. NHS identifies those children who need help, i.e. treating their deafness expeditiously, to achieve well-being in life.

A newborn baby is evaluated with an Apgar score to decide whether he/she needs immediate medical attention. Likewise, a newborn baby should be subjected to NHS before it leaves the hospital to work out a strategy for follow-up testing, if indicated. To comply with the principle of Fairness, NHS should be performed on all newborn babies and therefore institutions (hospitals) may have an opt-out policy. The huge potential benefit to the baby, its parents and society, justifies even mandatory NHS on all babies. Distributive justice demands that a deaf baby must be treated as soon as possible to lessen the impact on funds and resources available in society.

NHS may also be used to confirm deafness in a baby when his/her parents choose to have a deaf child, as discussed in the next chapter.

Chapter 4: Elective Deafness and Cochlear Implants

4.1 Background

Although the supporters of the Deaf community accept that deafness has some significant disadvantages, they view these disadvantages are social in character (Levy, 2002:138). They endorse the concept that deafness is not a disability in a specific society, i.e. the Deaf community, where deafness is in fact, viewed as normal. The Deaf community believes that medically treating deafness sends out a message that deaf people are inferior and need to be "fixed/enhanced" (Levy, 2002a:141). Many members of the Deaf community prefer not to use the term 'disability', but rather, 'differently-abled' (Davis, 1995: xiii). The Deaf society cherish their own, unique culture, even though they accept that it is a minority culture. They wish that it should not disappear; therefore, they want as many people as possible to belong to, or join, this culture. In an article in *The Washington Post* of March 2002, Liza Mundy discussed a deaf, lesbian couple's decision to use technology, Pre-implantation Genetic Diagnosis (PGD), to ensure that they have a deaf child. Spriggs (2002a:283) identified some support for this couple's decision, but mostly criticism. The availability of CIs influences the moral debate concerning this situation.

4.2 Physiology of Prenatal Diagnosis

Prenatal diagnostic procedures have been developed to diagnose birth defects or genetic disorders and if present, to give the parents the option of termination of the pregnancy. Cells are obtained for Cytogenetic evaluations with Chorionic villus sampling and Amniocentesis.

Chorionic villus sampling is performed between 10 and 14 weeks gestation period and entails harvesting cells from the placenta with a transcervical or transabdominal approach (Carlson and Vora, 2017:251). With **Amniocentesis,** amniotic fluid and cells, are obtained transabdominally, under ultrasound guidance, and is performed after 15 weeks gestation.

Preimplantation genetic diagnosis (PGD) allows for even earlier identification of chromosomal abnormalities. PGD is performed after in vitro fertilization (IVF) which comprises harvesting eggs after medically stimulating the ovaries. The eggs are then fertilized and placed in a petri dish and allowed to develop for three days until they reach the 8-cell stage. One cell from each embryo is removed and its DNA is examined for the presence of the chromosomal abnormality, and if present, this embryo is discarded. If the DNA is normal, the embryo is transferred to the mother's uterus to develop further (Lee, 2016:1-2).

4.3 Medical Facts

IVF and PGD are not without risks and their efficacy cannot be guaranteed. There is a risk for a multiple pregnancy, with all its own complications, of approximately 20%, according to Ramalingam et al (2016:206).

Hormonal stimulation to induce ovulation may cause Ovarian Hyperstimulation Syndrome (OHSS). A mild form of this syndrome is present in 33% of IVF patients and a moderate to severe form in up to 2% of patients. In the severe form patients present with thrombosis, renal and liver dysfunction, and acute respiratory distress syndrome or ARDS (Ramalingam et al, 2016:206). The exact incidence of mortality from OHSS is unknown but expected to be rare.

What the effect of removal of a cell from the embryo may have on the further development of the embryo and eventually the child, is unknown. PGD combined with IVF has a success rate (for a normal birth) of 66% compared to 48% for IVF alone (Scott et al, 2013: 700). Technical errors during the DNA amplification process may result in misdiagnoses in 19% of cases (DeUgarte et al, 2008: 1052) and thus implanting the incorrect/undesired embryo. Parents who would like to make use of PGD must be thoroughly counselled about the procedure, its limitations, and possible side-effects.

4.4 Ethical Issues with PGD

Preimplantation Diagnosis is used to identify genetic defects in an embryo, and to then prevent this embryo from developing into a child with a disability, by destroying this embryo. Only embryos without the genetic defect is implanted in the mother's uterus. This practice of discarding/destroying an abnormal embryo might be morally debatable, but infertility clinics do this regularly because these procedures were developed to select the genetically normal embryos.

Spriggs and Savulescu (2002:289) discussed an Australian couple's decision to use IVF, PGD and tissue typing (Human Leukocyte Antigen – HLA) to acquire a normal sibling for their three-year-old daughter who suffers from Fanconi's anaemia. This is a rare genetic condition which results in death before 15 years of age but can be successfully treated with umbilical cord blood from a perfectly matched sibling. The Infertility Treatment Authority (ITA) of Australia gave permission for the procedures but imposed certain constrictions: it can only be used to save a terminally ill sibling, only blood or bone marrow (no organs, such as kidneys) may be harvested from the donor child, and each application must be reviewed by the ITA. In England, the Human Fertilization and Embryology Authority (similar to ITA in Australia) regulates infertility treatment, and approves of IVF, PGD and tissue typing if it complies with strict criteria. In America, these procedures are used successfully. Some people criticized the couple because they see it as "a form of selective breeding", but they were also praised by others who saw their decision as "a triumph for common sense". The parents say: "We are not seeking to custom-design a baby, we just want permission to pick the one embryo that does not have the disease and is a compatible tissue match". This situation seems to be morally permissible because a normal embryo, although with certain characteristics (HLA compatible), is selected. Hall (2008:143) concluded that selective abortion of an abnormal fetus cannot be viewed as discrimination towards disabled persons, and therefore destroying abnormal embryos is also not discriminatory.

Another situation discussed by Spriggs (2002b:290) involves a 30 year old woman with a strong family history of Alzheimer's disease: her father died at age 42 with memory problems, her sister was institutionalized because of Alzheimer's at age 38, and her brother at age 35 had short term memory problems. Genetic tests showed that the patient, her brother and sister had the mutant gene (V717L) that codifies for early-onset Alzheimer's (Verlinsky et al,

2002:1019). Early-onset Alzheimer's is genetically inherited and affects people in their third and fourth decades. This mother, a geneticist, used IVF and PGD to select an embryo free of the mutant gene for Alzheimer's and thus gave birth to a normal child. She was ethically criticized for using these procedures to prevent a disease that affects people only later in life, when these procedures were developed to prevent childhood afflictions (Spriggs, 2002b:290). She was also criticized for having a baby at all, seeing that she will probably only be able to care for this child for 10 to 15 years. Verlinsky, co-author of the article in the Journal of the American Medical Association that first reported this case, apparently said: "Any difficulties the family might face are outweighed by the fact that the family's next generation will be free of the problem" (Spriggs, 2002b:290). Applying IVF and PGD to eliminate the presence, or *eventual* manifestation, of a disease seems morally justifiable.

A married, lesbian couple in America, who were both deaf because they carried the gene Connexin 26, which is believed to be responsible for 50% of all recessive cases of hearing loss, wanted a deaf child. They already had a five-year-old deaf daughter who was conceived with the help of In-vitro Fertilization, with the sperm from a deaf donor who comes from a family with five generations of deafness. They were both active members in the Deaf community and viewed deafness not as a disability, but a character trait (Lee, 2016:2). They, in fact, viewed a hearing child as problematic in their family and community. They requested the fertility clinic to use IVF and PGD to identify and implant a deaf embryo and to discard/destroy the other embryos without the gene for deafness. This case raises a few ethical questions: Is elective deafness morally justified? What is the role that Cochlear Implants play in elective deafness?

4.5 Ethics of Elective Deafness

The last couple successfully used IVF, with the sperm from a person who most likely had the mutant gene for deafness, to have their first child. It is a basic human right to procreate with whomever one wishes to. For their second child, they wanted to use IVF and PGD to ensure that they have another deaf child who will fit in with their family and the Deaf culture.

Lee (2016:4) states that the Roman Catholic Church does not accept or permit IVF or PGD because it views personhood to start at conception and therefore embryos are human beings

with rights. The Catholic Church also argues that it is immoral to produce human embryos that may eventually be managed as disposable biological material.

Arguments for or against elective deafness should keep the principles of Autonomy, Beneficence, Non-maleficence, and Justice in mind.

4.5.1 Autonomy

The Belmont Report views Respect for Persons as consisting of 1) acknowledging an individual's autonomy, and 2) protecting those with diminished autonomy (The Belmont Report, 1979:4). Lee (2016:4-5) states that one's definition of personhood influences one's moral view in connection with the destruction of embryos. If one's definition is that personhood begins at conception (like the Roman Catholic Church), then destruction of embryos violates the principle of respect for persons. Opponents believe that personhood begins when the fetus is viable or at birth, and therefore the embryos do not have any moral or legal rights. In elective deafness, embryos with normal genetic material are destroyed and Lee views this as a violation of a vulnerable, and eventually normal, person's human rights (2016:5). Conversely, choosing the embryo with the genetic mutation for deafness, will grant this child the opportunity to life, with all its benefits.

Reproductive decisions include a moral obligation to choose the child with the best possible prospects in life (Savulescu, 2002:772). Prospective parents are the only ones who must decide what are the best prospects in life for their future children. Savulescu quotes John Stuart Mill: "If a person possesses any tolerable amount of common sense and experience, his own mode of laying out his existence is the best, not because it is the best in itself, but because it is his own mode." Savulescu (2002:773) admits that selecting a disabled child is pushing the limits in Respect for Autonomy, but to impose our idea of what is best in life, is not only overconfident but might even be arrogant. Anstey (2002:287) defines a reproductive choice as whether a child should exist, not whether a particular child should exist, and therefore concludes that couples should select neither for, nor against, deafness.

4.5.2 Beneficence and Nonmaleficence

The principle of Beneficence refers to a moral obligation to act in such a way that others will benefit or that it will enhance and promote their good, or that it will minimize harm and risk to others. The principle of Nonmaleficence expects that we do not harm others, as expressed in the maxim Primum non nocere: "Above all (or first) do no harm." Nonmaleficence is an impartial principle, i.e. we must act nonmaleficently towards all people; whereas Beneficence is a partial principle, as we are obligated to act beneficently only to people we have a special relationship with, and not all people (Beauchamp and Childress, 2013:204).

To create a child with a genetic deafness is viewed by Lee (2016:5) to not minimizing risks and harms, and not promoting or enhancing the child's good. The parents therefore do not comply with their moral and legal right to act in their child's best interest. This 'created' disability will have an impact on the rest of the child's life and the child could not consent to this.

Levy (2002b:284) argues that it is difficult to decide whether the parent's decision to elect for deafness will limit her right to an open future, because we often decide on behalf of our children and this necessarily limits their freedom. Levy does admit that deafness is a disability, as we are a logocentric culture, with the result that a deaf person will always be disadvantaged to a certain degree. Levy states that a child born to deaf parents, who are active in the Deaf community, and has a deaf sibling, will give him/her access to the Deaf culture, whether he/she is deaf or not, because culture is viewed as a child's birthright. According to Levy (2002b:285) a hearing child will learn and use sign language if exposed to it regularly, and if also exposed to the spoken word, will be able to participate in both cultures, and therefore have maximum opportunities in life. Levy (2002b:285) therefore suggests that the couple have a normal hearing child whom they can expose to sign language and the spoken word. However, deaf parents choosing elective deafness were probably very isolated and alone as children and they want to spare their children similar experiences. We should therefore treat them with compassion and not condemnation.

4.5.3 Justice

The term justice includes fairness, desert (what is deserved) and entitlement. Beauchamp and Childress (2013:250) describe distributive justice as "…the fair, equitable, and appropriate distribution of benefits and burdens determined by norms that structure the terms of social cooperation." Aristotle said: Equals must be treated equally, and unequals must be treated unequally. Medical resources should therefore be distributed fairly, equitably, and appropriately. The parents electing for deafness in their child may argue that it is just for them to have a child who will fit in with their family and Deaf community and they must therefore be given their due. Critics of this argument state that creating a deaf child violates the child's rights for fair and equitable treatment, but also the rights of everyone in society, because the deaf child will use more medical, social and educational resources for the rest of his/her life (Lee, 2016:5) than a hearing child. Physicians are obliged to use available medical supplies/tests fairly and equitably. IVF and PGD were developed to assist parents to eliminate abnormal embryos and to now use this technology to select for an abnormal child, is ethically problematic.

4.5.4 Slippery-Slope argument

Although many people disregard slippery-slope arguments, Beauchamp and Childress (2013:179) warn that some of these arguments should be taken seriously. Lee (2016:5) is concerned that if this couple can choose a deaf child, other couples might choose to have a blind child or a Down's syndrome child or a child with some other genetic abnormality.

4.6 Elective Deafness with Cochlear Implant

The couple choosing a deaf child with the help of IVF and PGD, will argue that this is in the best interest of their child and it is the child's right, when he/she is older, to have a Cochlear Implant. The parents may also argue that if the deaf child does not fit in with their family and the Deaf community, they can request to have a CI for the child. Both these situations are medically and morally problematic.

Neuroplasticity during the first 3 years of a child's life (sensitive period) is responsible for development of new pathways in the brain if sound is not heard. For the best results with a CI, the device should be implanted as soon after 6 months as possible, but definitely before 3 years of age in prelingually deaf children (see page 13). To wait until the child is 12 years old, when he/she may legally give consent for an operation, and then have a CI, will result in extremely poor, if any, language development.

Because of this expected extremely poor result after 12 years of deafness, and the fact that it was an elective deafness, few, if any, CI-units will view such a child as a candidate for a CI. There are so many other children with deafness, caused by unavoidable diseases, who are young enough to maximally benefit by having a CI, that the principles of Distributive Justice and Fairness expect that time and resources should not be spent on children with elective deafness. The availability of a CI should therefore not be a factor in the parent's decision to elect for a deaf child, unless (facetiously) they want him/her to have a CI at 6 months of age, but then it is obviously easier and more beneficial to have a hearing child and raise him/her with sign language and spoken language. With this last option, the child will benefit from both the Deaf and spoken cultures, which will give him/her the most possible opportunities in life and therefore the best possible quality of life. This option will therefore be in the child's best interest.

Chapter 5: Vaccination Ethics

5.1 Introduction

The most common complication of measles is deafness (otitis media) and the most common cause of postlingual bilateral deafness in children is bacterial (Haemophilus influenzae and Streptococcus pneumoniae) meningitis. Mumps is the most common cause of postlingual severe, unilateral deafness in children, while maternal rubella infection forms part of 25% of environmental factors causing congenital deafness. All these infections can be prevented with vaccinations, thus making vaccination in the context of deafness and Cochlear Implants extremely relevant.

In 2017 the number of measles cases (21 315) in Europe increased 4-fold compared to 2016 (5273) and 35 deaths due to measles were reported (WHO, 2018). Lack of vaccination against measles is the reason for worldwide outbreaks of the disease, but developing countries are affected more and with more severe complications. Since the beginning of 2019 approximately 310 000 cases of measles have been reported in the Democratic Republic of the Congo and the death toll from this epidemic is more than 6 000 according to the WHO (7 January 2020). According to the Oxford Vaccine Group's website, 250 people die worldwide every day because of measles: 1 in every 5 000 infected people dies in high-income countries and 1 in 100 dies in the poorest regions of the world (Giubilini, 2019: ix). Opposition to vaccines is viewed by Giubilini (2019:10) as a first world problem because people in first world countries have the "luxury" of deciding whether to be vaccinated or have their children vaccinated. Their decision, whether to vaccinate or not, will however have consequences for the people in poorer countries where the complications of infectious diseases are more severe.

Vaccination is an enhancement according to Buchanan's definition (2011:23): "a deliberate intervention, applying biomedical science, which aims to improve an existing capacity that most or all normal human beings typically have".

Vaccination is not only an ethical issue but also a layered ethical issue because it provokes individual and collective/communal and state/institutional moral obligations. What an individual decides about vaccination (for him/herself or for their child) will have important

consequences not only for him/herself but also for the community, locally and globally. The state has an obligation to implement policies to vaccinate as many people as possible.

5.2 Physiology

Vaccination or immunization is the introduction into the human body of a weakened or dead pathogen that stimulates the body's immune system to produce antibodies against that pathogen. If the vaccinated person comes in contact with the infection, his/her immune system will prevent the disease. The vaccination is administered with an intramuscular or subcutaneous injection, oral drops or a nasal spray. Vaccines are not 100% effective and although the effectiveness can be determined with a blood test, it is impractical to test all vaccinated individuals. Effectiveness depends on how competent the individual's immune system is and on whether he/she received a booster dose of the vaccine. For example, the measles vaccine is 93% to 97% effective depending on the number of doses given (Giubilini, 2019:6). The vaccines that can prevent diseases which cause deafness are MMR, Prevenar 13 and Haemophilus influenzae type b vaccine.

MMR – protects against mumps, measles and rubella. It contains small amounts of the live viruses (weakened) and is administered as a subcutaneous injection at age 1 year, and again at 4 years. It may also be combined with a varicella (chickenpox) vaccine (MMRV). After the first dose it is 93% effective against measles, 78% against mumps and 97% against rubella. After the second dose it is 97% effective against measles and 88% against mumps. People with a weakened immune system due to a disease (cancer, HIV/AIDS, tuberculosis) or medical treatments (radiation, chemotherapy, immunotherapy, steroids) should not be vaccinated. Common side-effects include pain, redness, swelling at the injection site, moderate fever, faint rash, runny nose, cough, swollen glands. Very rare side-effects include convulsions due to high fever, bruising or bleeding at injection site, encephalitis (inflammation of the brain), anaphylactic (severe allergic) reaction.

Pneumococcal vaccines – ***Prevenar 13®*** and ***Pneumovax 23®*** protect against Streptococcus pneumoniae infections causing pneumonia, meningitis and ear infections. Prevenar 13® protects against 13 strains of Pneumococci and is given as an intramuscular injection at 6 weeks, 4 months and 12 months of age. Pneumovax® protects against 23 strains of Pneumococci and is also given as an intramuscular injection but only for children older than 2

years. Common side-effects may include pain at the injection site, mild fever or drowsiness. A severe allergic reaction to the vaccine is very rare.

Haemophilus influenzae vaccine – Hib vaccine protects against Haemophilus influenzae type b infection and is given by injection at 2, 4, 6, and 12 months. Haemophilus influenzae is the commonest cause of meningitis in children younger than 5 years.

A high rate of immunization in a community protects not only the individual persons who were vaccinated but also those persons who cannot be vaccinated because of medical reasons, for example, babies too young to be vaccinated and people with an immunodeficiency caused by malignancies, chemotherapy or radiotherapy. This is called herd immunity, community immunity, herd effect or population immunity. Herd immunity is achieved for measles when 90% to 95% of the population in a community is vaccinated against measles and for polio between 80% and 85%. If an infected person enters a community with herd immunity, the infection is very unlikely to spread and non-vaccinated individuals are therefore indirectly protected against infectious diseases. Herd immunity does not protect the individual against infections as well as individual vaccination, but for those not able to have vaccinations it is the best possible alternative. Increase in international travel threatens herd immunity but if each nation achieves herd immunity, global herd immunity is possible. The aim of vaccination is therefore twofold: individual protection and herd immunity.

Non-vaccination for non-medical reasons decreases the effect of herd immunity and increases the possibility of infection for those individuals who cannot be vaccinated. This choice, made out of self-interest, will have an effect on the interests of other people and society and therefore arguments for routine or compulsory vaccination are appropriate. Dawson (2011a:1029-1033) focuses on four arguments (balancing harm and benefits, best interest of the child, public /societal benefits and justice) in favor of routine vaccination of children and Giubilini (2019:1-126) has written a book to ultimately justify compulsory vaccination.

5.3 Harm and Benefits

The English philosopher John Stuart Mill (1806-1873) formulated the so-called harm principle in his book *On Liberty* (1859): "states or authorities may only use their power over any member of a civilized community, against his will, to prevent harm to others." Although vaccination may cause harm (side-effects) in a very small percentage of people, this misperception may influence parents not to vaccinate their children. If side-effects do occur, parents may feel responsible for the harm caused to their child, whereas harm caused by the disease itself is seen as "natural" and not the responsibility of the parent. Dawson (2011a:1030) states that preventing harm is always better than allowing the harm to develop and then treating it. Contracting measles in the developed world might be viewed as a trivial disease but, if a malnourished child in a poor society with low vaccination rates and limited access to health care, contracts measles, it may have devastating consequences. Parents deciding whether to vaccinate their incompetent children apply weak paternalism and this is morally justifiable. Health care workers working with people with immunodeficiencies (care homes) should be vaccinated against influenza to prevent harm to their patients. Dawson (2011b:145) states that as we have a moral obligation not to cause harm to others and if we can reduce the risk of causing serious harm to others, we are morally obligated to be vaccinated and have our children vaccinated.

It is important to balance harms and benefits when discussing vaccination policies. Dawson (2011a:1029) views vaccination as a perfect example of a public health issue because harms and benefits do not apply to individuals alone, but also to populations/communities/societies. When enough members of a community are vaccinated it creates herd immunity where all the members in that society are protected against infections.

5.4 Best Interests

In a democratic society individual liberty is very important. Parents have the liberty to make decisions in relation to their children's health and should be able to identify their own child's best interests. When parents make a decision about their child's care which is likely to result in significant harm to the child, a third party (the state) has an obligation to step in to protect the child from this harm. Dawson (2011b:146) concludes that parental decisions about their

children's non-vaccination may sometimes be justifiably overruled. The best interest standard should, however, also take into consideration the requirements and rights of others, according to Kling and Kruger (Moodley, 2017:218).

5.5 Community benefits

Except for granting individual benefits, vaccination programs are also beneficial to communities or populations via herd immunity, what Dawson (2011a:1031) prefers to call community-immunity. This community-immunity provides protection against infections to all the members of a society, even to those who cannot be vaccinated and those for whom the vaccination failed to create immunity. He views community-immunity as a Public and a Common good.

Public goods are commodities or services that benefit all the members of a society and that are created by many individuals, or government or state organisations. Examples are national defence, fire protection, public parks and street lighting. Public goods are indivisible (cannot be broken up and shared by contributors) and nonexcludable/non-rivalrous (no person in the group can be prevented from having the benefit). Dawson (2011b:149) states that where herd immunity is concerned, the individual's needs are not sacrificed for the well-being of the community, as vaccinated individuals will derive an additional benefit from herd immunity. Not contributing to such a public good/herd immunity (if medically possible), may be seen as free-riding, or unfairly profiting from the public good by not contributing, which is morally problematic.

Common goods. Members in a community have a social relationship with each other, requiring members to act in certain ways and to take one another's interests into consideration, that is, have mutual concern. Common goods make it possible to lead a flourishing and meaningful life together. The common good includes some of the basic requirements of social justice as citizens should afford one another basic rights and freedoms and not exploit each other. Common goods are the result of shared social norms and are not enforced. Creating and maintaining herd immunity is seen by Dawson (2011b:150) to be a common good because it reduces the risk of infections in a society which can be viewed as a common threat to our way of life. By vaccinating one's children, one is contributing to a communal project that will

benefit the whole society. He says: “A society with a commitment to common goods is clearly in the best interests of a child”. Vaccination also results in financial benefits for a community because: 1) prevention of a disease is cheaper than treating the disease and its complications, and 2) if the disease can be eradicated, a long-lasting saving is achieved by not having to vaccinate against the disease anymore.

5.6 Justice

The term justice can be explained as involving fairness, desert (what is deserved) and entitlement. It requires of us to treat persons fairly, equitably and appropriately according to what is due or owed to them. The beneficial effects of relatively inexpensive vaccination can be seen in individuals as well as communities, more pronounced in developing countries. Justice arguments are relevant to vaccination as not all children in the world have the opportunity to be vaccinated and this opportunity is indirectly proportionate to the risk of acquiring the disease and its complications (Dawson, 2011a:1032).

Vaccinating as many people in the world as possible will help towards achieving equity in global health. Justice therefore requires that wealthier countries subsidize vaccination programs in poorer countries. To argue that funding a vaccination program in a country faraway does not benefit one, is incorrect as increase in international travel facilitates global spread of infectious diseases, as illustrated by the recent pandemic with the Coronavirus SARS-CoV-2, causing COVID-19. The increase in international travel makes it difficult to determine in which community herd immunity should be achieved, as the world can be viewed as one big community.

Dawson (2011a:1032) states that the best-interests argument and justice provide a rationale for implementing compulsory/routine vaccination, especially where the infection poses a high risk of harm.

5.7 Non-vaccination

Some individuals have a medical reason why they should not be vaccinated, for example, very young children and persons with an immunodeficiency, but there are people who can be vaccinated, but prefer not to be. These people are referred to as "anti-vaxxers". This term applies to a group of people who are against vaccination for themselves or their children for various reasons. On the spectrum between vaccine acceptance and vaccine refusal there are people who deny the safety of vaccines (vaccine denialists) and people who are just not sure that vaccines are safe and/or effective (vaccine hesitancy). The ethical formula, "Ought implies can", ascribed to Immanuel Kant (1724-1804) who stated in *Critique of Pure Reason* (1781) that a person, if morally obliged to perform a certain action, must also logically, be able to perform it, can be applied to vaccination: if it is possible to be vaccinated, it ought to be done. On the other hand, some people cannot be vaccinated for medical reasons or logistical reasons – they might not be able to travel to a clinic for vaccinations.

5.7.1 Vaccine hesitancy

Vaccine hesitancy can be defined as: a behavior, influenced by a number of factors including issues of confidence (do not trust vaccine or provider), complacency (do not perceive a need for a vaccine, do not value the vaccine), and convenience (access) according to Larson et al (2014:2151). The WHO's Strategic Advisory Group on Experts (SAGE) on Immunization defines vaccine hesitancy as "…. a delay in acceptance or refusal of vaccination despite availability of vaccination services. Vaccine hesitancy is complex and context specific, varying across time, place, and vaccines". People's concepts of vaccination are dynamic and may change over time, therefore, Larson et al (2015:4170) suggest survey tools to gain insight into people's (changing) opinions about vaccinations.

In South Africa, 5% of people believe that vaccines are unnecessary, 9% believe vaccines are unsafe and 11% believe vaccines are ineffective (Cooper et al, 2020:11). In their review of parents' and caregivers' experience of communication about childhood vaccination, Ames et al (2017:29) found that parents regarded the information they received as being inadequate. The level of acceptance of vaccination determined the amount of information parents wanted

– parents who were hesitant about vaccination, had delayed vaccination or decided not to vaccinate, required more information and also more detail about vaccination. 74% of South Africans trust doctors and nurses for medical advice according to a recent Wellcome Global Monitor report (Cooper et al, 2020:11). Cooper et al therefore concluded that enabling health care workers to confidently and competently promote vaccination is important to achieve effective communication with parents and this in turn will improve vaccination rates.

Giubilini (2019:13) discuss four factors that may explain vaccine failures: sociological, epistemic, cultural and psychological.

Sociological – whether socio-economic status plays a role in vaccine decisions is uncertain. Wang et al (2014: e64) found two studies that showed parents wanting nonmedical exemption from vaccinations are more likely to be from higher socioeconomic groups. In contrast, they also identified two studies that showed vaccine refusals come from lower socioeconomic groups.

Epistemic – parents may doubt the efficacy and/or safety of vaccines. They perceive, incorrectly, that the risk of getting the disease from the vaccination is greater than contracting the disease naturally, or that contracting the disease results in a better immune system than getting vaccinated.

Cultural – some cultural or religious groups may oppose vaccination, but these are in the minority, according to Giubilini (2019:15).

Psychological – taking into consideration the benefits and possible disadvantages of vaccination, one would expect rational people to decide on vaccination or have their children vaccinated. Therefore, Giubilini (2019:16) argues that vaccine refusal has an irrational component, and this is the result of bias. Omission bias (the tendency to view the negative outcome because of inaction preferable than the same outcome caused by an action) and naturalness bias (the tendency to prefer natural products even when they are worse than the synthetic alternative) may play a role in vaccine refusal. Anti-vaxxers may (irrationally and incorrectly) argue that: 1) contracting an infectious disease is preferable to experiencing the side-effects of vaccination, and 2) it is better (for immunity) to be infected by the natural organism than the synthetically produced organism present in vaccinations.

5.8 Herd Immunity Responsibility

Accepting the benefits of vaccination not only for the individual, but also for the creation and maintenance of herd/community immunity, the question arises, whose responsibility is herd immunity? Giubilini (2019:30) suggests three possible agents who are ethically obliged to maintain herd immunity: individuals, collectives and institutions. One's refusal to be vaccinated or to have one's children vaccinated (one has the right to make autonomous decisions) could cause other people harm by exposing them to a preventable infectious disease (public health) and thus violating the harm principle. Giubilini (2019:36) applies the term "duty of easy rescue" to vaccination: we have a moral duty to do something (be vaccinated) that requires only a slight discomfort from us, but that can prevent harm to others (no/insufficient herd immunity). The contribution of each individual to herd immunity is minimal, but if as many people as possible are vaccinated, herd immunity can be achieved. Thus, the realization of herd immunity must be a collective responsibility of the community. He qualifies collective by saying herd immunity requires individuals to enter into aggregate individual actions and not coordinated group actions. An aggregate is a mass or body of units or parts, loosely associated with one another: froth is an aggregate of tiny bubbles. He states that achieving herd immunity is an aggregate collective responsibility: each and every member of the collective, who is able to contribute to herd immunity, has a moral obligation to do so, that is, being vaccinated or have one's children vaccinated. The responsibility to contribute to herd immunity (be vaccinated) must be distributed fairly among those individuals who can be vaccinated (principle of fairness). He states that the state is justified in requesting people to be vaccinated for the purpose of achieving herd immunity because it (the state) is not asking individuals to do something supererogatory.

5.9 Compulsory/Routine Vaccination

According to the Nuffield Council on Bioethics (2007:53) some of the goals of routine vaccination are: to protect as many individuals as possible in a population, to protect vulnerable or at-risk individuals (for example, annual influenza vaccine for health care workers or for travelers to an area where specific infections are common), to develop and maintain herd/population immunity.

Dawson (2011b:151) is of the opinion that compulsory vaccination will only be necessary in a society that values individual liberty above all other valuable considerations, for example, freedom from possible harm to others. Indirect compulsion, for example, having vaccination as a requirement for enrolling in school, is preferable to Direct compulsion which involves legal sanctions such as fines. Using the powers of the state to interfere in a family where preventative rather than therapeutic actions are concerned, is not appropriate. However, the effects of the (preventable) infectious disease can be severe and even deadly, especially in the developing world. Parents' right to refuse and a child's right to bodily integrity may be seen as not as important as avoiding harm to others. He states that parents do not have an absolute right to do what they want with their children because the best interests of the child must always be the priority.

During humanitarian emergencies, when there is a higher risk of transmission of infectious diseases, vaccination is more important than when there is no emergency. Moodley et al (2013:293) suggest that during emergencies, informed consent by parents for vaccination of their children may be modified to speed up the vaccination effort in a community. Authorities may even mandate vaccination of children against parental wishes.

The Nuffield Council on Bioethics (2007:41) devised an intervention ladder to categorize different public health policies according to their intrusiveness on autonomy. The more intrusive on autonomy, the more justification for a certain policy is necessary. The benefits to society must be weighed against the weakening of individual autonomy. They describe the increase in intrusiveness on autonomy as follows:

1. on the lowest rung of the ladder is doing nothing or merely monitoring the situation, the least intrusive option.
2. next is to supply information to educate the public.
3. empower people to change their behavior, for example, building bicycle lanes.
4. Manipulate choices to change the default option, for example, making it more attractive to buy healthy foods (nudging).
5. manipulate choices with incentives, for example, tax-breaks for buying a bicycle to cycle to work.
6. disincentives to do something harmful, for example, taxing cigarettes.
7. limit choices to protect people, for example, removing unhealthy foods from shops.

8. at the highest rung of the ladder is total elimination of choice, for example, compulsory isolation of infectious patients, fluoridation of drinking water to protect teeth.

The function of the intervention ladder is to compare the different available options with respect to their level of intrusiveness and possible acceptability.

The primary goal of Public health remains the health of the whole population and not the health of individuals. To address the conflict between the moral considerations in the goals of public health and other moral responsibilities when setting up policies, Childress et al (2002:173) suggest five "justificatory conditions": effectiveness, proportionality, necessity, least infringement and public justification.

Effectiveness – will infringing on individuals' moral considerations be of benefit to public health?

Proportionality – will the benefit to public health outweigh the infringement? i.e. balancing the benefits against the negative effects. In other words, is it worth the infringement?

Necessity – infringing on general moral considerations must be required to achieve the public goal, i.e. an alternative strategy will probably not be effective, but must be considered.

Least infringement – public health authorities should try to minimize the limiting effect on general moral considerations by using the least restrictive alternative (Principle of Least Restrictive Alternative, PLRA).

Public justification – public health authorities have a responsibility to explain and justify the infringement to those who are affected by the intended policy. Transparency creates and maintains public trust.

Giubilini (2019:60) uses the Principle of Least Restrictive Alternative, PLRA, and the "Intervention Ladder", to list the possible public health measures available to realize herd immunity. The restrictiveness of any type of intervention is context specific, i.e. it depends on, for example, the psychology of targeted individuals or their socio-economic situation.

Figure 5: Graphic presentation of Intervention Ladder and PLRA

Supplying information about vaccination to people who mistrust health care professionals is unlikely to be successful, as is nudging of parents with deeply religious or philosophical convictions. Knowledge of the specific reasons for vaccination hesitancy or refusal is thus very important. Giubilini (2019:64) mentions that policies should consider the number of people whose autonomy is limited as well as the degree of limitation on these people. He proposes a combination of these criteria, according to the so-called maximin rule: the preferred policy is the policy with the least restriction on the autonomy of the people who are affected by the restriction. The preferred policy is one where the number of people whose autonomy is less/not restricted, is much larger than those whose autonomy is restricted.

He ranks possible vaccination policies in increasing levels of restriction on those whose autonomy is restricted by the policy. Voluntary vaccination is the least restrictive option and

compulsory vaccination the most restrictive with a spectrum of different options in between, from persuasion to nudging to incentives to disincentives.

Giubilini (2019:67-69) distinguishes between coercion and restriction. He psychologically defines coercion as the influence of a specific policy on a person's will where the person is forced to do something without having a reasonable choice in the matter or an acceptable alternative. The person is pressurized into doing something by subjecting him/her to the will of another person. Coercive actions therefore restrict another person's autonomy. Coercive interventions may use penalties or threats and sometimes rewards/incentives where the degree of coercion is lower with incentives than with penalties. A policy can be restrictive without being coercive because restricting a person's autonomy still leaves him/her reasonable choices and/or acceptable alternatives. The concept of restrictiveness is therefore broader than that of coercion. Both concepts are context specific, i.e. what a person is forced to do is also important: for example, being coerced into having one's children vaccinated is less restrictive than being coerced to donate one's kidney.

5.9.1 Persuasion

Persuading people to be vaccinated or have their children vaccinated, by educating them about the benefits and possible side-effects of vaccination, tries to influence or change people's behavior. The individual can still decide whether he/she wants to be subjected to the information. It is thus not manipulative and not coercive and maintains the individual's autonomy to choose whether to vaccinate their child or not.

Hough-Telford et al (2016:4) found that 74% of parents who refused vaccination for their children believed that vaccines are unnecessary and 64% were concerned about a possible link between vaccination and autism caused by thimerosal in vaccination products. (Thimerosal is an organic mercury which was used for its antiseptic and anti-fungal properties to preserve vaccine solutions. Since 1999 thimerosal is not allowed in vaccine solutions although it was never shown to have a link to autism). Education/Persuasion should be successful in dispelling these misperceptions. Parents with a religious or philosophical opposition to vaccinations will probably not be persuaded by education and may need policies with more influence on personal decision making. Persuasion is the bottom rung of Giubilini's (2019:70) intervention ladder because it does not involve restriction or coercion.

5.9.2 Nudging

A nudge is defined by Thaler and Sunstein (2008: p6) as a way of presenting choices that "alter people's behavior in a predictable way without forbidding any option or significantly changing their economic incentives". A nudge is manipulative but not coercive, because the individual does have a reasonable choice and an acceptable alternative (Giubilini, 2019:73). Thaler and Sunstein (2008: p5) use the term "libertarian paternalism" to justify nudges. "Libertarian" because individuals are still free to do what they prefer as all options are available to them. "Paternalistic" refers to the persons/institutions setting up the options to try to influence people's behavior to improve their lives. The status quo bias, where people's preference is to do nothing, can be used to set up the default effect where the default option applies when a person does not make a definitive choice. For example, parents will be informed that all children will be vaccinated at school by a doctor or nurse, except if the parents opt-out for their children. If they do nothing, parents unconditionally authorize vaccination of their children. This nudging targets those parents who are positive about vaccination but do not act on their intentions for whatever reasons. Giubilini (2019:76) argues that nudging will only influence parents who are not convinced non-vaxxers and therefore infringing on their autonomy is not morally problematic. Nudging, because of its minimal restrictiveness, comes above persuasion on Giubilini's intervention ladder.

5.9.3 Incentives

Offering financial incentives (so-called conditional cash transfers, CCT's) to get vaccinated or have your children vaccinated, will be coercive to at least some people. Paying people to do something (getting vaccinated) they do not desire, or will, can be viewed as an unwelcome offer (Giubilini, 2019:77). Large financial incentives will limit the decision-making capacity of vulnerable people, i.e. those with a low income, as it leaves them with no other reasonable choice or acceptable alternative. Conflicting evidence exist for the effectiveness of financial incentives to promote vaccination (Giubilini, 2019:79) and it may cause "crowding out" of motivation for the incentivized choice, i.e. people may think the incentivized option is so unpopular that people must be paid/bribed to take that option. Financial incentives to vaccinate one's children depend on the context in which they are given. Its restrictiveness and coercion

make incentives morally more problematic than nudging or persuasion and thus incentives are above nudging on the intervention ladder.

5.9.4 Disincentives

The rationale for using penalties to promote vaccination uptake rests on two related psychological phenomena: loss aversion and endowment effect.

Loss aversion – Thaler and Sunstein (2008:36) state that "losing something makes you twice as miserable as gaining the same thing makes you happy". Thus, paying a fine/penalty for not complying with vaccination requirements will hurt parents more than receiving an incentive.

Endowment effect – Goods already in our possession have a bigger value for us than goods we do not yet possess.

Using loss aversion and the endowment effect to impose a penalty for non-vaccination is more coercive than giving incentives for vaccinating one's children. Ethically speaking, threats are considered worse than offers and thus need a higher level of justification. The influence that threats and offers have on individuals depends on the size of the prospective threat or offer. Giubilini (2019: 83-87) discusses three types of penalties or disincentives in increasing order of restrictiveness: Withholding of Financial Benefits, Taxation and Denying enrolment in school and day care for non-vaccination.

Withholding of Financial Benefits – Parents who do not vaccinate their children are not entitled to childcare benefits from the state. This policy was effective in Australia in 2016: ***The Guardian***, *'No jab, no pay': thousands immunize children to avoid family payment cuts, 31 July 2016.* It may be seen to be both an incentive and a penalty to have one's child vaccinated, so is therefore more restrictive and coercive on people's decision-making abilities than incentives. In some people the withholding of financial benefits may have loss aversion and endowment effects similar to financial penalties. Applying the PLRA, withholding financial benefits from parents who do not vaccinate their children, should only be used if persuasion, nudging and incentives are ineffective.

Tax – taxing non-vaccination behavior will hopefully discourage such behavior by forcing people to assimilate the cost of non-cooperation. This affects autonomous decision-making

more than withholding of benefits. Taxing non-vaccination should only be implemented if persuasion, nudging, incentives or withholding financial benefits are ineffective in achieving herd immunity.

Mandatory Vaccination: Denying Enrolment in School, Day care – withholding certain social services is more coercive and restrictive than withholding financial benefits and taxation. Navin and Largent (2017: 226) distinguish between compulsory and mandatory vaccination: compulsory vaccination is where parents must legally comply with a policy, whereas mandatory vaccination parents are legally free not to vaccinate their children. The freedom to not vaccinate their child will not only cost the parents financially but will also have a psychosocial impact on the child's development if he/she does not attend day care and/or school, although parents may initiate home-schooling, which is time-consuming. Mandatory vaccination often leaves the parents with no reasonable choice and no acceptable alternative and is therefore more coercive than being penalized with taxation or the withholding of financial benefits. Giubilini (2019:87) doubts whether mandatory vaccination has a long-term effect on the vaccination rate and he therefore suggests compulsory vaccination as a last resort.

5.9.5 Compulsion

Making it illegal not to vaccinate is the most restrictive and coercive vaccination policy. It differs from mandatory policies in that there are legal consequences to non-vaccination and it being illegal not to vaccinate, justifies hefty, i.e. very burdensome, penalties. Breaking the law will also set a strong psychological barrier for non-vaccination. The influence on people's autonomy is a lot more than with taxation or mandatory vaccination. As compulsion is the most restrictive option, to comply with the PLRA, all other options must have been proved unsuccessful in realizing herd immunity. Compulsory vaccination is thus the last resort if the primary goal of immunization is achieving and maintaining herd immunity.

5.10 Fairness and Compulsory Vaccination

The principle of fairness is acknowledged and respected by most people and is in accord with common moral beliefs. Most reasonable people will endorse it when certain burdens need to be distributed. Giubilini (2019:102) uses the harm principle of John Stuart Mill and links it to fairness by quoting Mill, saying: "This conduct consists in each person's bearing his share of the labours and sacrifices incurred for defending the society or its members from injury and molestation" (Mill 1859, p140-141). Fairness may be understood as meaning equality, where everyone is burdened to the same extent, irrespective of the capability to bear that burden. Fairness may also mean equity, where everyone is burdened according to his/her capability to bear the burden. Vaccinating everybody who does not have a medical contraindication for vaccination, represents equitable fairness. He states that fairness is an important ethical and social value when sharing burdens necessary to preserve public goods. He claims that fairness is an ethical value standing independently from other values involved in setting policies, like individual liberty and expected utility, i.e. in achieving herd immunity. Fairness is one of the goals of vaccination policies (the other: realizing herd immunity), while PLRA is a method of deciding which option is suitable to achieve these goals. He further states that (p108) the least restrictive policy that would fairly realize and maintain herd immunity is probably 'unqualified compulsory vaccination'. Fairness is also socially important because it affects people's actions which in turn influences the realization of important public goods. People need the assurance that burdens are distributed fairly. People are willing to contribute their fair share (carry a burden, i.e. being vaccinated) to public goods to achieve an objective (herd immunity) if they know that others are doing the same. Evidence from neuroscience and psychology shows that there is a link between being treated fairly and positive emotions that inspire people to participate in collective campaigns. Compulsory vaccination will distribute the 'burden' of vaccination fairly and equitably and is according to Giubilini (2019:114) the ethically and obligatory policy to endorse.

Exemption from vaccination for non-medical reasons (conscientious objection) may threaten herd immunity if the numbers are too large. Clarke et al (2017: 159) justifies an analogy between conscientious objections concerning military conscription and vaccination. It is therefore crucial to regulate conscientious objections. Navin and Largent (2017:230) endorse what they call the "inconvenience" model which was implemented successfully in Michigan. Parents who refused vaccination of their children for nonmedical reasons had to attend

immunization education classes presented by the local public health department and had to use an official state form to apply for exemption. Within one year after implementation of these measures in Michigan, the exemption rate decreased by 39%. Giubilini et al (2017:237) propose the "contribution" model which incorporates inconvenience. According to this model, parents who want exemption from vaccination for their children should make a contribution to public health that is equal to the benefit of vaccination to public health. They argue that parents who refuse vaccination for their children should not only endure burdens, like attending educational classes, but should also simultaneously contribute to a public health benefit. Giubilini (2019:119) argues that if we accept that fairness in the allocation of the burdens (vaccination) of herd immunity should be a goal of vaccination policies, allowing some people non-medical exemption from vaccination would violate the fairness principle. The ultimate conclusion (p121) of his book, *The Ethics of Vaccination,* is that unqualified compulsory vaccination is ethically justified, and this should be enforced by the state.

Dawson (2011b:151) says that authorities may consider compulsory vaccination when 1) public health structures are poorly developed, 2) there is little or no feeling of social solidarity in a society, 3) individual freedom is the most important criterion for setting public policies. He states: "A society without what we might call active social values is a failing society". A society is impoverished if it must depend on the state to coerce/force its members to accept their moral obligations whereas, in a society with healthy values, compulsion is not necessary.

5.11 Conclusion

Infectious diseases have the potential to harm humans, especially the very young, old and immunocompromised individuals, by causing severe complications. Children are more vulnerable to these infections, and their complications, because of their immature immune systems. These immature immune systems can be manipulated by vaccines to the benefit of the child for the rest of his/her life. Children depend on their parents and society to act in their best interests. Vaccinating enough children against a specific infectious disease creates herd immunity whereby children who cannot be vaccinated because of medical reasons, are also protected against the infection. Those who can be vaccinated have an individual benefit but also help those who cannot be vaccinated. Those who can be vaccinated should carry the

‘burden’ of vaccination to comply with the principle of Fairness. Vaccination can thus be seen as not only a privilege, but also a duty to the community.

Children in poorer countries often cannot be vaccinated because of logistical reasons, but they are also more susceptible to infectious diseases and the disease complications are more severe because of poor nutrition. International travel has made the world a ‘global village’ and therefore developed countries have a responsibility to, 1) have as many of their own children vaccinated, and 2) subsidize vaccination programs in developing countries. This will satisfy the principle of Justice and will attempt to achieve equity in global health.

Local health care authorities are therefore morally justified in implementing compulsory vaccination programs, but in complying with the Principle of Least Restrictive Alternative, at least mandatory vaccination of children, although the principle of Fairness demands compulsory vaccination.

Chapter 6: Summary

6.1 Deafness, an Enhanceable Disability

Pediatric deafness has a profound effect not only on a child's speech development, but also on his/her global neurological development and social integration. Without auditory stimulation during the first three years of a child's life (so-called sensitive period), the brain re-organizes itself to use other sensory inputs to compensate for the deafness, i.e. neuroplasticity. Thus, Pediatric deafness is a disability, but one that demands urgent attention to prevent significant harm to the child.

The diagnosis of deafness in a newborn baby is usually unexpected by the parents and they may see it as a loss of the expectation of a 'normal' baby and go through a grieving process similar to a death experience. Fortunately, with the help of modern technology, parents do have excellent options available to help their deaf children develop normally, in a community that offers the child all the benefits of a normal hearing child. To assist deaf children to develop optimally, parents can choose between a CI or Sign language, the latter as part of the Deaf community. A Cochlear Implant treats a child's severe or profound sensorineural deafness very effectively, on condition that it is implanted as soon as possible. Hearing parents of a deaf child are under no obligation to support or maintain the Deaf community by teaching their child Sign language. Parents, as the surrogate decision makers of the newborn deaf child, should decide which option is best for their child, but they must be comprehensively informed about both options, because it is a decision that will permanently influence the child's future. The parents must also guard against being influenced, or coerced, to take a decision that they are not fully committed to. Teaching your child Sign language demands a lot of patience and is time-consuming, as is the rehabilitation after a CI. A CI, however, ensures that the deaf child has all the opportunities in life that a hearing child has.

6.2 Elective Deafness

Choosing to have a child with a genetic deafness is possible, but the morality of this decision is debatable. Medical technology, In Vitro Fertilization and Preimplantation Genetic Diagnosis, were developed to avoid children being born with genetic abnormalities. Although one may argue that this practice discriminates against children born with a disability, it has become morally acceptable as it affords the normal child the opportunity to life.

People belonging to the Deaf culture want to use this technology to ensure that they have a deaf child. These parents argue that a deaf child will effortlessly become part of their family and community, because the child will be exposed to, and therefore learn, Sign language to communicate. The principle of Autonomy gives the parents the right to decide on the type of child they want because they should know what is in the best interest of their future child in their own, unique environment. However, a hearing child born to deaf parents will have the opportunity to develop with sign and spoken language, and this will maximize the child's opportunities in life and therefore satisfy the principle of Beneficence. The parents, designing deafness, a disability, in a child are harming and putting the child at risk without the child being able to consent to this, and they therefore do not comply with the principle of Nonmaleficence. As surrogate decision makers for their, as yet unborn child, parents must comply with the principle of the best interest for their child and make a decision that offers the greatest net benefit to their child. Choosing a child with deafness does not support this principle.

Creating a deaf child who will use more community resources during his/her life and using technology that was developed to ensure normal babies, is not fair and compromise the Justice principle.

Parents choosing to have a deaf child and arguing that the child may later in life decide him/herself to have a CI, are not offering their child a feasible alternative to the situation they put their child in. Having a CI after three years of deafness requires intense rehabilitation to achieve near normal speech development, but after 12 years, normal speech development is almost impossible. A CI is a relative scarce resource that involves life-long rehabilitation and therefore CI-units need to prioritize candidates for CIs and thus a patient with a 'created' deafness will find it difficult to be accepted by any unit. It is unfair

on the child to be placed in such a situation and therefore the parents cannot use the availability of a CI (that gives the child the opportunity to reverse their faulty decision) to justify electing deafness.

The morality behind elective deafness provokes a lot of discussion, which is essential, as advances in medicine, for example genome editing with CRISPR/Cas9, also creates similar ethical problems.

6.3 Newborn Hearing Screening

Newborn children are young, vulnerable human beings. The United Nations Convention on the Rights of the Child (1990:4) states in Article 3, "In all actions concerning children….the best interests of the child shall be a primary consideration." And, in Article 6, "State Parties shall ensure to the maximum extent possible the survival and development of the child." It is therefore our obligation to ensure the newborn baby is treated with his/her best interests in mind and thereby facilitate optimal development.

A congenital deafness cannot be diagnosed with a routine neonatal examination, but Newborn Hearing Screening will identify those children with a possible deafness who can then be comprehensively, audiologically, evaluated. Newborn Hearing Screening causes little or no discomfort to the baby but may lead to a tremendous benefit, by ensuring normal development, if deafness is diagnosed early and treated promptly. Every newborn baby is entitled to a thorough examination, which should include NHS, before discharge from hospital or alternatively, during a follow-up visit at a clinic. Early diagnosis of deafness is crucial for prompt initiation of treatment, especially if the parents decide on a CI. NHS satisfies the principle of Justice by: promoting social utility (identifying and treating deafness early), ensuring fair distribution of 'good' in the community, giving the newborn access to a valuable commodity (CI), giving the deaf newborn the capability to thrive in life, and ensuring the newborn's well-being by treating the deafness as soon as possible. NHS is generally performed by an audiologist, who is in a professional-patient relationship with the newborn child's surrogate decision maker, usually the mother. This relationship can become challenging if the mother becomes incompetent and the next possible family member is not available or decides contrary to what the mother would have wished. The

best interests of the newborn baby should however, always prevail. Other third parties may also influence the availability and application of NHS, for instance, policies of hospitals and medical insurers, but again, the priority should always be the best interest of the newborn baby. Doing NHS is always in the best interest of the newborn baby and ought therefore to be done on all newborns, but the logistics of doing so may be a challenge, especially in developing countries.

6.4 Vaccination Ethics

Vaccination modulates/improves an individual's immune system and is thus an enhancement. If enough individuals are vaccinated, it also creates herd-immunity which may be viewed as an enhancement of communities, locally, but also globally. Easily accessible international travel facilitates the rapid spread of infections, as demonstrated by the pandemic caused by the SARS-CoV-2 causing Covid-19. Therefore, for a vaccination program to be effective, it needs to be implemented globally.

Preventing deafness-causing diseases with vaccinations is a much better option, for the individual child and the community, than treating the deafness and other complications resulting from these infections. Treating infections and their complications may have devastating effects on a country's economy, which can easily affect global economy if many countries are involved, for example, the Covid-19 pandemic. Saving resources by not having to treat infections, upholds the principle of Justice.

The obligation to be vaccinated resides not only in the individual (or parents of a child), but also in the state/government who should ensure that enough individuals are vaccinated to maintain herd-immunity and thereby also protect those individuals who cannot be vaccinated. Recently, some parents have decided, for various reasons, not to vaccinate their children against childhood viral infections, like mumps, measles, rubella and bacterial infections, like Pneumococcal infections. These parents prioritize their own children's best interests by avoiding the (small) risk attached to vaccination, but in doing so, are causing harm to others by not contributing to herd-immunity, which is a Public and a Common good. The principle of Justice requires that those who can be vaccinated, should do so.

Institutions (state/government) are justified in using strategies to encourage individuals to be vaccinated or have their children vaccinated. These strategies are for the benefit of society and may infringe on individual autonomy. The least intrusive intervention should be tried first, and if not successful, more intrusive options may be tried, adhering to the Principle of Least Restrictive Alternative (Childress et al, 2002:173). Also applying an Intervention Ladder (Nuffield Council on Bioethics, 2007:41), policies to encourage vaccination may include (from the least intrusive to the most intrusive): Persuasion, Nudging, Incentives, Disincentives, Mandatory and ultimately, Compulsion.

The principle of Fairness demands that the 'burden' of being vaccinated should be distributed fairly throughout the population. Everybody who can be vaccinated should do so to distribute the responsibility fairly. Voluntary vaccination is the ideal, but if this is not enough to create and maintain herd-immunity, compulsory vaccination policies may justifiably be instituted.

Vaccinations should be accessible, and even freely available, to everybody in the world, especially to people in poorer/developing countries, because these countries can least afford to treat the infections. The ease and frequency of international travel, which may facilitate the unchecked spread of infections, has forced countries to realize that public health initiatives, for example vaccination programs, are not only national concerns, but should be implemented internationally.

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